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Transitional Care Interventions to Prevent Readmissions for People with Heart Failure

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies and strategies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To improve the scientific rigor of these evidence reports, AHRQ supports empiric research by the EPCs to help understand or improve complex methodologic issues in systematic reviews. These methods research projects are intended to contribute to the research base in and be used to improve the science of systematic reviews. They are not intended to be guidance to the EPC program, although may be considered by EPCs along with other scientific research when determining EPC program methods guidance.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality. The reports undergo peer review prior to their release as a final report.

We welcome comments on this Methods Research Project. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to epc@ahrq.hhs.gov.

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Key Informants

In designing the study questions, the EPC consulted several Key Informants who represent the end-users of research. The EPC sought the Key Informant input on the priority areas for research and synthesis. Key Informants are not involved in the analysis of the evidence or the writing of the report. Therefore, in the end, study questions, design, methodological approaches, and/or conclusions do not necessarily represent the views of individual Key Informants.

Key Informants must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their role as end-users, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any conflicts of interest.

Key Informants

The list of Key Informants who participated in developing this report follows:

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Technical Expert Panel

In designing the study questions and methodology at the outset of this report, the EPC consulted several technical and content experts. Broad expertise and perspectives were sought. Divergent and conflicted opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore, in the end, study questions, design, methodologic approaches, and/or conclusions do not necessarily represent the views of individual technical and content experts.

Technical Experts must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

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Peer Reviewers

Prior to publication of the final evidence report, EPCs sought input from independent Peer Reviewers without financial conflicts of interest. However, the conclusions and synthesis of the scientific literature presented in this report does not necessarily represent the views of individual reviewers.

Peer Reviewers must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential non-financial conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential non-financial conflicts of interest identified.

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Transitional Care Interventions to Prevent Readmissions for People with Heart Failure

Structured Abstract

Objectives: To conduct a systematic review and meta-analysis of the efficacy, comparative effectiveness, and harms of transitional care interventions that aim to reduce early readmissions and mortality for adults hospitalized with heart failure (HF). We also sought to describe the shared components of interventions that showed efficacy.

Data Sources: MEDLINE®, Cochrane Library, CINAHL®, ClinicalTrials.gov, and World Health Organization International Clinical Trials Registry Platform (January 1, 1990 to early May, 2013).

Review Methods: Two investigators independently selected, extracted data from, and rated risk of bias of relevant randomized controlled trials. We conducted meta-analyses using random-effects models to estimate pooled effects. We graded strength of evidence (SOE) based on established guidance.

Results: We included 47 trials. Most included patients with moderate to severe HF; mean ages of patients were in the 70s. Few trials reported 30-day readmission rates. High intensity ome-visiting programs reduced all-cause readmission and the combined endpoint of all-cause readmission or death at 30 days (low strength of evidence [SOE]). Home-visiting also reduced all-cause readmission rates (3 and 6 months), HF-specific readmission rates (3 months), and combined endpoint all-cause readmission or death (6 months) (moderate SOE). Structured telephone support (STS) interventions reduced HF-specific readmission rates (3 and 6 months) and mortality (6 months) (moderate SOE). Multidisciplinary (MDS)-HF clinic interventions reduced all-cause readmission rates and mortality (both 6 months) (moderate SOE). The number needed to treat to prevent 1 all-cause readmission ranged from 5 to 12 for home-visiting programs over 1 to 6 months, and was 7 for MDS-HF clinic interventions over 3 to 6 months. Current evidence does not establish the efficacy of telemonitoring or primarily educational interventions for reducing readmissions or mortality.

Components of interventions showing efficacy for reducing all-cause readmissions or mortality include: HF education, emphasizing self-care; HF pharmacotherapy, emphasizing promotion of adherence and evidence-based HF pharmacotherapy; and a streamlined mechanism to contact care delivery personnel (e.g., patient hotline). In general, categories of interventions that reduced all-cause readmissions or mortality were more likely to be of higher intensity, to be delivered face-to-face, and to be provided by multidisciplinary teams.

Conclusions: Our results suggest that home-visiting programs, STS, and MDS-HF clinic interventions currently have the best evidence supporting their efficacy for reducing readmissions and/or mortality, and should receive the greatest consideration by systems or providers seeking to implement interventions to improve transitional care for patients with HF.

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Executive Summary

Background

Heart failure (HF) is a major public health problem and a leading cause of hospitalization and health care costs in the United States. It is the most common principal discharge diagnosis among Medicare beneficiaries and the third highest for hospital reimbursements, according to 2005 data from the Centers for Medicare & Medicaid Services (CMS).[1] Up to 25 percent of patients hospitalized with HF are readmitted within 30 days.[2-5]

In an effort to reduce the frequency of rehospitalization of Medicare patients, in October 2012 CMS began lowering reimbursements to hospitals with excessive risk-standardized readmission rates as part of the Hospital Readmissions Reduction Program authorized by the Affordable Care Act.[6] This policy provides incentives for hospitals to develop effective transition programs to reduce readmission rates for people with HF.

Nearly 7 million Americans 18 years of age and older were diagnosed with HF in 2010; an additional 3 million Americans will have the condition by 2030.[7,8] The incidence of HF increases with age; it affects 1 of every 100 people after 65 years of age.[9] Coronary disease and uncontrolled hypertension are the two highest population-attributable risks for HF.[10] Survival after HF diagnosis has improved over time, as shown by data from the Framingham Heart Study[11] and the Olmsted County Study.[12] However, the death rate remains high: 50 percent of people diagnosed with HF die within 5 years after diagnosis.[11,12] Among Medicare beneficiaries, more than 30 percent of patients with HF die within 1 year after hospitalization.[13] National data show no evidence that readmission rates for HF patients have fallen during the past 2 decades, despite the observation that HF hospitalizations in the United States have declined by almost 30 percent during the past decade.[14]

In 2007, the Medicare Payment Advisory Commission called for hospital-specific public reporting of readmission rates, identifying HF as a priority condition. The Commission stated that readmissions for HF were common, costly, and often preventable.[15] An estimated 12.5 percent of admissions for HF were potentially preventable.[16]

Readmissions following an index hospitalization for HF appear to be related to various conditions. An analysis of 2007 to 2009 Medicare claims data reported that 35.2 percent of readmissions within 30 days were for HF; the remainder of readmissions were for diverse indications (e.g., renal disorders, pneumonia, arrhythmias, and septicemia/shock).[5]

The relationship between readmission rates and other important outcomes (e.g., mortality, emergency room [ER] visits) is unclear. Some data suggest that hospitals with the lowest mortality rate among patients with HF tend to have higher readmission rates.[17]

Transitional Care Interventions for People with Heart Failure

Interventions designed to prevent readmission among patients with HF are often referred to as "transitional care interventions."[18,19] Naylor and colleagues defined transitional care as "a broad range of time-limited services designed to ensure health care continuity, avoid preventable poor outcomes among at-risk populations, and promote the safe and timely transfer of patients from one level of care to another or from one type of setting to another" (p.747).[18] Transitional care interventions overlap with other forms of care (primary care, care coordination, discharge planning, disease management, and case management); however, they aim specifically to avoid poor clinical outcomes arising from uncoordinated care.[20]

No clear set of intervention components defines transitional care interventions. They tend to focus on the following: patient or caregiver education (including education on self-management, e.g., self-titrating diuretics), medication reconciliation, coordination with outpatient providers, arrangements for future care (e.g., home health, outpatient followup), and symptom monitoring or reinforcement of education during the transition (e.g., home visits, telephone support, or additional outpatient visits).

No clear consensus exists about when the transition period ends. Although evaluating 30-day readmissions is important for certain stakeholders (hospitals, payers, quality improvement organizations), outcomes beyond this period are clinically important and may benefit from overall improvements in care. Outcomes far away from the index hospitalization probably reflect the natural history of HF or an unrelated illness, rather than a preventable readmission related to the transition of care.

Existing Guidance

The 2013 American Heart Association/American College of Cardiology (AHA/ACC) Heart Failure guidelines addressed postdischarge HF interventions.[21] These guidelines focus on the importance of optimizing HF pharmacotherapy prior to discharge, providing HF education prior to discharge (including self-care), and addressing barriers to care among other factors. Specifically, the following components were noted as reasonable post-discharge care options: a follow-up visit within 7 to 14 days of dishcarge and/or a telephone follow-up within 3 days of discharge.[21]The AHA/ACC guidelines also recommend initiating multidisciplinary HF disease management programs for patients at high risk for readmission. The 2010 Heart Failure Society of America guidelines are similar; their guidance emphasizes particular components of discharge planning.[22] No specific guidance is given on the optimal components of transitional care interventions aimed at preventing readmissions for patients with HF.

Several national performance measures pertain to the standard of care for hospital discharge of HF patients. The Joint Commission performance measures mandate that all patients with HF should receive comprehensive, written discharge instructions or other educational materials that address activity level, diet, discharge medications, follow-up appointment, weight monitoring, and planned actions to take should symptoms worsen.[23] These measures are publicly reported by hospitals. In 2011, the ACC/AHA/AMA (American Medical Association) Performance Consortium added a documented postdischarge appointment to the list of recommended HF performance measures.[24] Required documentation includes location, date, and time for a follow-up office visit or home health care visit.

Scope and Key Questions

An assessment of the efficacy, comparative effectiveness, and harms of transitional care interventions is needed to support evidence-based policy and clinical decisionmaking. Despite advances in the quality of acute and chronic HF disease management, gaps remain in knowledge about effective interventions to support the transition of care for patients with HF.

To address these issues, we conducted a systematic review and meta-analysis of investigations of transitional care interventions for adults with HF. Our report focuses mainly on transitional care interventions that aim to reduce early readmissions and mortality for patients hospitalized with HF; we also examine several related issues, including potential harms of such interventions. Specifically, we address the following five Key Questions (KQs):

KQ 1: Among adults who have been admitted for heart failure, do transitional care interventions increase or decrease the following health care utilization rates:

a. Readmission rates
b. Emergency room visits
c. Acute care visits
d. Hospital days (of subsequent readmissions)?

KQ 2: Among adults who have been admitted for heart failure, do transitional care interventions increase or decrease the following health and social outcomes:

a. Mortality rate
b. Functional status
c. Quality of life
d. Caregiver burden
e. Self-care burden?

KQ 3: This question has three parts:

a. What are the components of effective interventions?
b. Among effective interventions, are particular components necessary?
d. Among multicomponent interventions, do particular components add benefit?

KQ 4: This question has three parts:

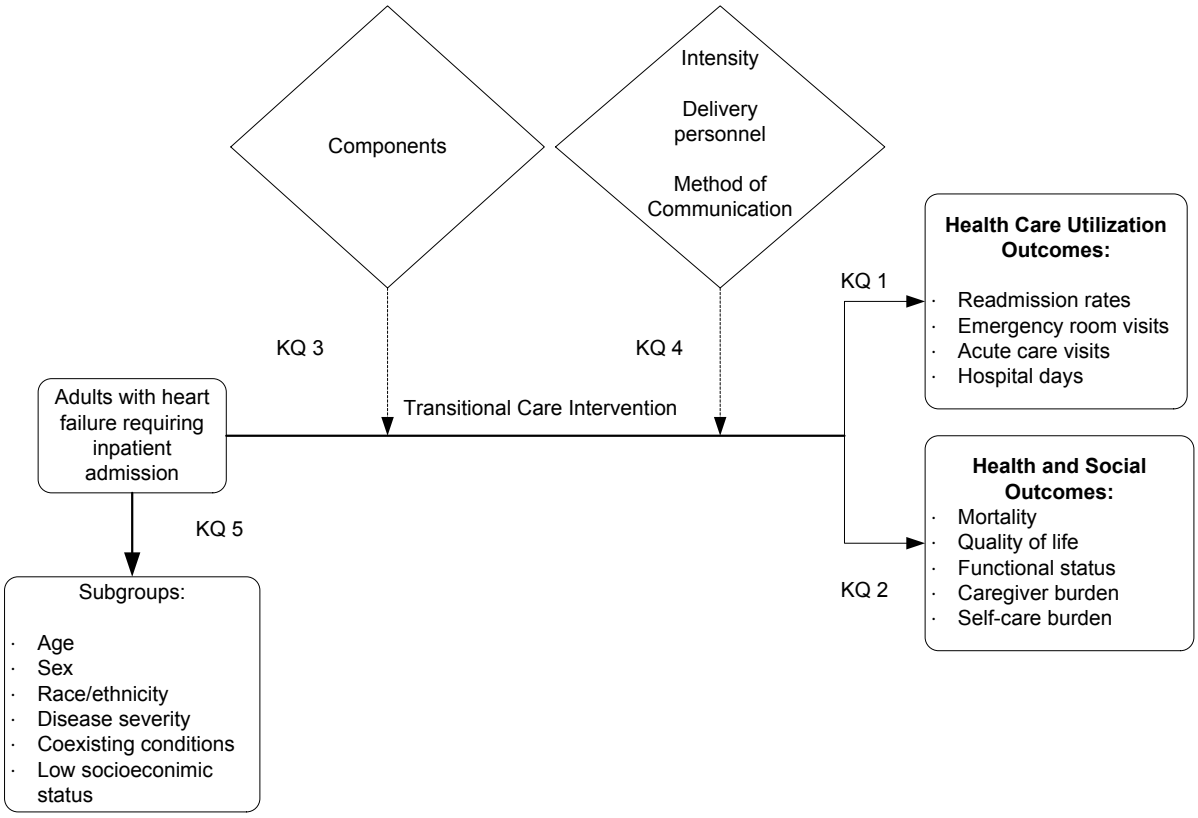
a. Does the effectiveness of interventions differ based on intensity (e.g., duration, frequency, or periodicity) of the interventions?
b. Does the effectiveness of interventions differ based on delivery personnel (e.g., nurse, pharmacist)?
c. Does the effectiveness of interventions differ based on method of communication (e.g., face-to-face, telephone, Internet)?

KQ 5: Do transitional care interventions differ in effectiveness or harms for subgroups of patients based on age, sex, race, ethnicity, disease severity (left ventricular ejection fraction or New York Heart Association classification), coexisting conditions, or socioeconomic status?

Analytic Framework

We developed an analytic framework to guide the systematic review process (Figure A).

Figure A. Analytic framework for transitional care interventions to prevent readmissions in people with heart failure



Methods

Literature Search Strategy

We searched MEDLINE®, the Cochrane Library, and the Cumulative Index to Nursing and Allied Health Literature (CINAHL)® for English-language and human-only studies published from July 1, 2007 to May 9, 2013 and used a previous Agency for Healthcare Research and Quality (AHRQ) Technology Assessment on a similar topic to identify randomized controlled trials (RCTs) published before July 1, 2007.[25] We also searched the same electronic databases for relevant nonrandomized trials or prospective cohort studies that measured caregiver or self-care burden from 1990 to May 5, 2013. An experienced Evidence-based Practice Center (EPC) librarian conducted the searches and another EPC librarian peer-reviewed them. We manually searched reference lists of pertinent reviews, included trials, and background articles on this topic to look for any relevant citations that our searches might have missed. We searched for unpublished studies relevant to this review using ClinicalTrials.gov and the World Health Organization's International Clinical Trials Registry Platform.

Eligibility Criteria

We developed inclusion and exclusion criteria with respect to populations, interventions, comparators, outcomes, timing, and setting (PICOTS) and study designs. Briefly, we included

studies of adults with HF requiring inpatient admission that recruited subjects during or within 1 week of the index hospitalization. We required studies to compare a transitional care intervention aimed at reducing readmissions with another transitional care intervention or with usual care (i.e., routine care or standard care, as defined by the primary studies). We required that transitional care interventions include one or more of the following components: education to patient or caregiver (or both), delivered pre- or postdischarge (or both), discharge planning, appointment scheduling before discharge, increased planned or scheduled outpatient clinic visits (primary care, multidisciplinary HF), home visits, telemonitoring (including remote clinical visits), telephone support, transition coach or case management, or interventions to increase provider continuity.

This review focuses on the primary outcomes of readmission rates and mortality. We also evaluated the following outcomes when studies assessing readmission rates or mortality reported them: ER visits, acute care visits, hospital days (of subsequent readmissions), quality of life, functional status, and caregiver or self-care burden. We required a length of followup of at least 30 days and we included outcomes occurring no more than 6 months from the index hospitalization. We included only studies that assessed interventions applicable to patients who were discharged to home (and not another health care facility).

RCTs were eligible for all KQs. For caregiver burden and self-care burden outcomes, nonrandomized controlled trials or prospective cohort studies with an eligible comparison group were also eligible.

Study Selection

Two members of the research team independently reviewed each title and abstract (identified through searches) to determine eligibility. Studies marked for possible inclusion by either reviewer and those that lacked adequate information to determine eligibility underwent a full-text review. Two members of the team independently reviewed each full-text article to determine eligibility. If the reviewers disagreed, they resolved conflicts by discussion and consensus or by consulting a senior member of the team.

Data Extraction

We designed and used structured data extraction forms to gather pertinent information from each article, including characteristics of study populations, settings, interventions, comparators, study designs, methods, and results. Trained reviewers extracted the relevant data from each included article; a second member of the team reviewed all data abstractions for completeness and accuracy.

Risk of Bias Assessment of Individual Studies

To assess the risk of bias (internal validity) of studies, we used predefined criteria based on the AHRQ *Methods Guide*.[26] We assessed selection bias, confounding, performance bias, detection bias, and attrition bias; we included questions about adequacy of randomization, allocation concealment, similarity of groups at baseline, masking, attrition, whether intention-to-treat (ITT) analysis was used, methods of handling missing data, reliability and validity of outcome measures, and treatment fidelity. We rated the studies as low, medium, high, or unclear risk of bias.[26] Two independent reviewers assessed the risk of bias for each study. Disagreements

between the two reviewers were resolved by discussion and consensus or by consulting a third member of the team.

Categorization of Interventions

We grouped studies of similar interventions for our evidence synthesis. The American Heart Association provides a taxonomy of disease management that specifies eight domains: patient population, intervention recipient, intervention content, delivery personnel, method of communication, intensity and complexity, environment, and clinical outcomes.[27] We applied this taxonomy in categorizing intervention types based primarily on the mode and environment of delivery (Table A). We felt this method of categorization would best address the needs of multiple stakeholders who may be interested in interventions that could be implemented in specific health care settings. Most of the studies included components delivered both during hospitalization and after discharge.

Table A. Categories and definitions of transitional care interventions

Category	Definition
Home-visiting programs	Home visits by clinicians such as a nurse or pharmacist who deliver education, reinforce self-care instructions, perform physical examination, or provide other care (e.g., physical therapy, medication reconciliation). These interventions are often referred to as nurse case management interventions but also can include home visits by a pharmacist or multidisciplinary team.
Structured telephone support	Monitoring, education, and/or self-care management using simple telephone technology after discharge in a structured format (e.g., series of scheduled calls with a specific goal, structured questioning, or use of decision support software).
Telemonitoring	Remote monitoring of physiological data (e.g., electrocardiogram, blood pressure, weight, pulse oximetry, respiratory rate) with digital, broadband, satellite, wireless, or Bluetooth transmission to a monitoring center, with or without remote clinical visits (e.g., video monitoring).
Outpatient clinic-based interventions	Services provided in one of several different types of outpatient clinics—multidisciplinary HF, nurse-led HF, or primary care clinic. The clinic-based intervention can be managed by a nurse or other provider and may also offer unstructured telephone support (e.g., patient hotline) outside clinic hours.
Primarily educational interventions	Patient education (and self-care training) delivered predischarge or upon discharge by various delivery personnel or by modes of delivery: in-person, interactive CD-ROM, video education. Interventions in this category do not feature telemonitoring, home visiting, or structured telephone support; they are not delivered primarily through a clinic-based intervention (described above). Follow-up telephone calls may occur to ascertain outcomes (e.g., readmission rates) but not for monitoring.
Other	Unique interventions or interventions that did not fit into any of the other categories (e.g., individual peer support for HF patients).

Abbreviations: CD-ROM = Compact Disc Read-Only Memory; HF = heart failure.

Data Synthesis

We conducted meta-analyses using random-effects models to estimate pooled effects. For binary outcomes, we calculated risk differences (RDs) between groups. For continuous outcomes (e.g., scales of quality of life or function) measured with the same scale, we report the weighted mean difference between intervention and control subjects. When multiple scales were combined in one meta-analysis, we used the standardized mean difference (SMD), Cohen's d. For readmission rates, we conducted meta-analyses of studies that reported the number of people readmitted in each group. We stratified analyses for each intervention category by timing—to provide pooled point estimates for interventions at different time points following an index hospitalization. We did not include studies rated as high or unclear risk of bias in our main

analyses, but did include them in sensitivity analyses (for KQ 1 and KQ 2). We calculated the chi-squared statistic and the I^2 statistic (the proportion of variation in study estimates due to heterogeneity) to assess statistical heterogeneity in effects between studies.[28,29] When quantitative synthesis was not appropriate (e.g., because of clinical heterogeneity, insufficient numbers of similar studies, or insufficiency or variation in outcome reporting), we synthesized the data qualitatively.

For KQ 3, we synthesized the evidence qualitatively by first extracting detailed information on intervention components, content, and processes and then describing common components and combinations of components that were effective in reducing all-cause readmissions or mortality. We defined effective interventions as: (1) intervention categories (defined in Table 2 in Methods) that reduced all-cause readmissions (from our meta-analyses for KQ 1) or the combined endpoint of all-cause readmission or death; (2) intervention categories that reduced mortality in in our meta-analyses; (3) individual trials in other categories that were efficacious for reducing all-cause readmissions, mortality or the combined endpoint. Few studies reported outcomes at 30 days; below we describe the components of interventions that showed efficacy at any eligible time point (up to 6 months following an index hospitalization for HF).

For KQ 4, we conducted meta-analyses stratified by intensity, delivery personnel, and method of communication within each intervention category when variation existed. For KQ4, we only included studies rated as low or medium risk-of-bias.

Strength of the Body of Evidence

We graded the strength of evidence (SOE) to answer KQs as high, moderate, low, or insufficient using the guidance established for the EPC program.[30] Developed to grade the overall strength of a body of evidence, the approach incorporates four key domains: risk of bias (includes study design and aggregate quality), consistency, directness, and precision of the evidence. It also considers optional domains. Two reviewers assessed each domain for each key outcome and determined an overall SOE grade based on domain ratings. SOE grades are specified as high, moderate, low, or insufficient to convey the confidence we have that effect estimates reported is close to the true effect of an intervention. Insufficient is used to indicate that evidence is either unavailable, does not permit estimation of an effect, or does not permit us to draw a conclusion with at least a low level of confidence. In the event of disagreements on the domain rating or overall grade, they resolved differences by discussion or by consulting an experienced investigator. We graded the SOE for the following outcomes: all-cause readmissions, HF-specific readmissions, a combined end-point (all-cause readmission or death), mortality, ER visits, length of hospital stay (for all-cause readmissions), quality of life, and functional status.

Applicability

We assessed applicability of the evidence following guidance from the *Methods Guide.*[31] We used the PICOTS framework to explore factors that affect applicability.

Results

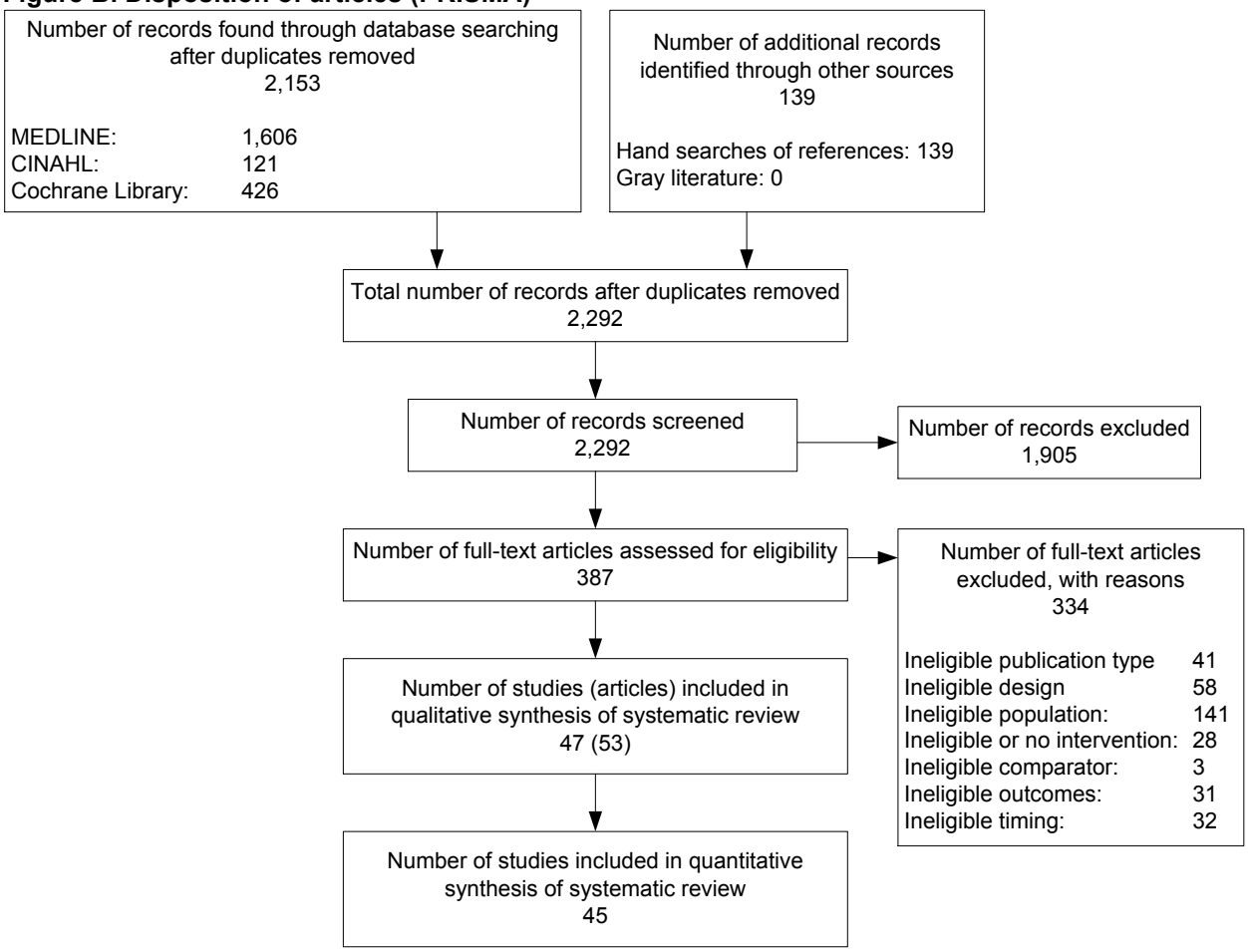
We included 53 published articles reporting on 47 studies; all were RCTs (Figure B).

We grouped trials of similar interventions based primarily on the mode and environment of delivery (see Table A above): home-visiting programs (15 RCTs), STS (13 trials), telemonitoring

(8 trials), outpatient clinic-based interventions (7 trials), and primarily educational interventions (4 trials). We also included two unique interventions in an "other" category; one featured "individual peer support" and one emphasized cognitive training for patients with coexisting mild cognitive impairment.

Most trials compared a transitional care intervention with usual care; only two trials (both rated high risk of bias) directly compared more than one transitional care intervention. Usual care was somewhat heterogeneous across trials and often not well described. In general, trials included adults with moderate to severe HF. The mean age of subjects was generally in the 70s; very few studies enrolled patients who were, on average, younger or older. Across most included trials, the majority of patients were prescribed an angiotensin-converting enzyme inhibitor

Figure B. Disposition of articles (PRISMA)



(ACEI) or angiotensin receptor blocker (ARB) (when information was reported); however, the percentages of patients across trials who were prescribed beta-blockers at discharge varied widely. In general, studies did not report on details of usual care. Included trials were conducted in a mix of settings, including academic medical centers, Department of Veterans Affairs (VA) hospital settings, and community hospitals.

Efficacy for Reducing Readmissions and Mortality

We found very little evidence on whether interventions reduce 30-day readmissions. Most studies reported rates over 3 or 6 months. One home-visiting trial showed efficacy in reducing all-cause readmission and the combined outcome (all-cause readmission or death) at 30 days.[32] Despite having only a single trial of home visiting that reported rates at 30 days, this intervention category also consistently reduced readmission rates over 3 and 6 months; therefore, we considered home-visiting programs efficacious in reducing both all-cause readmissions and the combined outcome all-cause readmission or death at 30 days (low SOE). Evidence was insufficient to determine whether the following intervention types reduced 30-day all-cause readmissions (1 trial each; none showed efficacy): structured telephone support (STS), telemonitoring, and cognitive training. We found no eligible trials of other types of interventions that reported 30-day all-cause readmission rates.

Table B summarizes our main findings and strength of evidence for 3- and 6-month readmission rates and mortality for timepoints with at least low SOE to support a conclusion. We found the best evidence of efficacy for improving our primary outcomes for home-visiting programs, STS, and multidisciplinary (MDS)-HF clinic interventions.

Table B. Summary of findings and strength of evidence for transitional care interventions: Readmission rates and mortality

Intervention Category	Outcome	Timing, months	N Trials; N Subjects	Risk Difference (95% CI)[a]	Numbers Needed to Treat	Strength of Evidence
Home-visiting	All-cause readmission	1	2; 418	High intensity interventions: -0.20 (-0.29, -0.10)	5	Low[b]
Home-visiting	All-cause readmission	3	4; 798	-0.12 (-0.18, -0.05)	8	Moderate
Home-visiting	All-cause readmission	6	5; 1102	-0.10 (-0.16, -0.05)	10	Moderate
Home-visiting	HF-specific readmission	3	1; 282	-0.14 (-0.23, -0.04)	8	Moderate[c]
Home-visiting	Composite endpoint[d]	1	1; 239	Hazard ratio (SE): 0.869 (0.033) vs. 0.737 (0.041)	NA[e]	Low[f]
Home-visiting	Composite endpoint	3	1; 239	Hazard ratio (SE): 0.071 (0.045) vs. 0.558 (0.047)	NA	Low[g]
Home-visiting	Composite endpoint	6	4; 824	-0.10 (-0.18, -0.02)	10	Moderate
Home-visiting	Mortality	30 days	1; 239	0.00 (-0.03, 0.03)	NA	Low[g]
Home-visiting	Mortality	3	2; 482	-0.02 (-0.06, 0.03)	NA	Moderate
Home-visiting	Mortality	6	5; 972	-0.04 (-0.09, 0.01)	NA	Moderate
STS	All-cause readmission	2 to 3	5; 1,024	-0.04 (-0.10, 0.03)	NA	Moderate
STS	All-cause readmission	6	6; 1,768	-0.06 (-0.16, 0.03)	NA	Low
STS	HF-specific readmission	3	5; 1,605	-0.04 (-0.07, -0.00)	25	Moderate
STS	HF-specific readmission	6	4; 677	-0.10 (-0.17, -0.03)	10	Moderate
STS	Composite endpoint	6	2; 866	-0.14 (-0.41, 0.13)	NA	Low
STS	Mortality	2 to 3	3; 618	-0.04 (-0.08, 0.00)	NA	Moderate
STS	Mortality	6	8; 1,724	-0.04 (-0.07, -0.01)	25	Moderate
Telemonitoring	All-cause readmission	2 to 3	2; 252	-0.00 (-0.12, 0.12)	NA	Moderate
Telemonitoring	All-cause readmission	6	1; 182	0.11 (-0.02, 0.24)	NA	Moderate[h]
Telemonitoring	HF-specific readmission	6	1; 182	0.08 (-0.03, 0.18)	NA	Moderate[h]
Telemonitoring	Mortality	3	2; 284	0.00 (-0.10, 0.10)	NA	Low
Telemonitoring	Mortality	6	2; 462	0.01 (-0.22, 0.24)	NA	Low

Table B. Summary of findings and strength of evidence for transitional care interventions: Readmission rates and mortality (continued)

Intervention Category	Outcome	Timing, months	N Trials; N Subjects	Risk Difference (95% CI)[a]	Numbers Needed to Treat	Strength of Evidence
MDS-HF clinic	All-cause readmission	6	2; 336	-0.15 (-0.26, -0.05)	7	Moderate
MDS-HF clinic	Composite endpoint	6	2; 306	-0.11 (-0.21, 0.00)	NA	Moderate
MDS-HF clinic	Mortality	6	3; 536	-0.07 (-0.12, -0.01)	13	Moderate
Primarily Educational	Composite endpoint	6	2; 423	-0.05 (-0.29, 0.20)	NA	Low
Primarily Educational	Mortality	6	2; 423	0.02 (-0.07, 0.10)	NA	Low

[a] Entries in this column are RDs from our meta-analyses or risk difference calculations unless otherwise specified. Negative risk differences favor interventions over controls.

[b] Two home-visiting programs reported all-cause readmission at 30 days; the intervention studied by Naylor and colleagues was of higher intensity and showed efficacy. The lower intensity intervention studied by Jaarsma et al. did not show efficacy at 30 days (low SOE; NNT= NA).

[c] Although only one trial reported total number of people readmitted per group, we considered the findings consistent because one other trial reported on the number of readmissions per group and found a similar effect: patients receiving home visits had fewer total HF readmissions than did patients receiving usual care (measured as readmissions per patient year alive, relative risk, 0.54; $p<0.001$; N=200).[33]

[d] All-cause readmission or death.

[e] NA entry for numbers needed to treat (NNT) indicates that the risk difference (95% CI) was not statistically significant, so we did not calculate a NNT. NA for hazard ratios indicates that we could not calculate a NNT with the data provided by the investigators.

[f] Although only a single trial reported the number of people alive and not readmitted at 30 days and 3 months, we considered the consistency of similar programs reducing 3-month readmissions rates when grading the SOE for this intervention at 30 days.

[g] Although evidence was limited to 1 trial, consistency for the 30-day outcome was unknown, and evidence was imprecise, we upgraded the SOE because this intervention category has demonstrated no effect on mortality at 3 or 6 months—thus, increasing our confidence in the results of this single trial.

[h] Although only a single trial reported on the number of people readmitted, we considered this finding consistent given that four other telemonitoring studies reported the total number of readmissions per group (rather than the number of people readmitted); all-cause readmissions did not differ between patients receiving telemonitoring and those receiving usual care at 30 days,[34] 3 months,[35] or 6 months.[34,36,37]

Abbreviations: CI = confidence level; MDS-HF, multidisciplinary heart failure clinic; N = number; NA = not applicable; NNT = number needed to treat; RD = risk difference; SE = standard error; SOE = strength of evidence; STS = structured telephone support.

Specifically, we found that home-visiting programs reduced 30-day all-cause readmissions and the 30-day combined endpoint (low SOE). For other outcome timings, we found the following (all moderate SOE): that home-visiting programs reduced all-cause readmission rates (3 and 6 months), HF-specific readmission rates (3 months), and the combined endpoint all-cause readmission or death (6 months); STS interventions reduced HF-specific readmission rates (3 and 6 months) and mortality (6 months); and MDS-HF clinic interventions reduced all-cause readmission rates and mortality (both over 6 months).

For these outcomes, numbers needed to treat (NNTs) ranged from 5 to 12 for home-visiting programs, from 10 to 25 for STS interventions, and from 7 to 13 for MDS-HF clinic interventions (Table B). For example, a NNT of 10 signifies that 10 people with HF would need

to receive a home-visiting program following discharge (rather than usual care) to prevent one additional person from being readmitted over 3 months.

Our meta-analyses did not find telemonitoring or primarily educational interventions to be efficacious for any primary outcomes. In addition, our meta-analyses did not find home-visiting programs efficacious for reducing mortality at 30 days (low SOE) or 3 and 6 months (moderate SOE) or STS interventions efficacious for reducing all-cause readmissions (low SOE). Evidence was insufficient to support the efficacy of the following interventions in reducing readmission rates or mortality: most primarily educational interventions, nurse-led HF clinic interventions, primary care clinic interventions, peer support interventions, and cognitive training interventions (for people with HF and coexisting mild cognitive impairment).

Some experts have cautioned that inappropriate focus on reduction of readmission rates could negatively affect patient care and perhaps mortality. However, we found no evidence of such an effect—i.e., no interventions that reduced readmission rates but increased mortality.

Other Utilization Outcomes

Few included trials reported on ER visits or hospital days of subsequent readmissions; when these were reported, few trials reported measures in the same manner or at similar timepoints. No included trials reported the number of acute outpatient (non-ER) visits.

For ER visits, we generally found insufficient evidence to determine whether transitional care interventions increased or decreased ER visits. The one exception was that STS interventions had no effect on the rate of ER visits over 6 months (low SOE).

For hospital days of subsequent readmissions, both home-visiting programs and STS reduced the total number of all-cause hospital days over 3 and 6 months (low SOE for both interventions). Otherwise evidence was insufficient to determine whether transitional care interventions increased or decreased hospital days of subsequent readmissions.

Quality of Life

Few trials measured quality of life or function using the same measures at similar timepoints. We found improvement in HF-specific quality of life (as measured by the Minnesota Living With Heart Failure (MLWHF) questionnaire was greater for home-visiting programs than usual care over 3 months (low SOE). Intervention and control groups did not differ on quality of life (MLWHFQ) for patients receiving home visits or primarily educational interventions at 6 months and for patients receiving STS over 3 and 6 months (both low SOE). Evidence was insufficient to determine whether other transitional care interventions improved quality of life.

Components of Effective Interventions

The two categories of interventions that reduced all-cause readmissions and the composite outcome—namely, home-visiting programs and MDS-HF clinic interventions—are multicomponent, complex interventions. We found no single-component intervention that reduced all-cause readmissions. As a whole, these two categories of interventions shared the following components:

- HF education emphasizing self-care, recognition of symptoms, and weight monitoring.

- HF pharmacotherapy emphasizing patient education about medications, promotion of adherence to medication regimens, and promotion of evidence-based HF pharmacotherapy before discharge or during followup (or both).
- Face-to-face contact following discharge via home-visiting personnel, MDS-HF clinic personnel (or both). In most cases, this contact occurred within 7 days of discharge.
- Streamlined mechanisms to contact care delivery personal (clinic personnel or visiting nurses or pharmacists) outside of scheduled visits (e.g., patient hotline).
- Mechanisms for postdischarge medication adjustment. In most cases, home-visiting personnel either directly recommended medication adjustment or assisted with coordination of care (e.g., with primary care provider or cardiologist) to facilitate timely medication adjustment based on a patient's needs (rather than advising patients to call for help themselves).

Two categories of interventions reduced mortality rates: STS (over 6 months), and MDS-HF clinic interventions (over 6 months). Both STS and MDS clinic interventions are multicomponent. As a whole, these two categories of interventions shared the following components:

- HF education emphasizing self-care, recognition of symptoms, and weight monitoring.
- A series of scheduled, structured visits (via telephone or clinic followup) that focused on reinforcing education and monitoring for HF symptoms.
- A mechanism to contact providers easily outside of scheduled visits (e.g., patient hotline).

Separating out individual components from the overall categories (or "bundles") of interventions that showed efficacy was not possible.

Intensity, Delivery Personnel, and Mode of Delivery

In general, intervention categories that included higher-intensity interventions (i.e., home-visiting programs, STS, MDS-HF clinic interventions) reduced all-cause readmissions or mortality, whereas categories with lower-intensity interventions (i.e., primarily educational interventions, nurse-led HF clinic interventions) did not. Within categories, evidence was generally insufficient to draw definitive conclusions about whether higher- or lower-intensity interventions are more or less efficacious in reducing all-cause readmissions or mortality. The one exception was home-visiting programs; higher intensity programs were effective in reducing all-cause readmission at 30 days while lower intensity programs were not effective. Subgroup analyses found no significant difference in efficacy based on intensity for home-visiting programs or STS. Subgroup analyses were not possible for other categories of interventions because of either lack of variation or too few trials reporting outcomes at similar timepoints.

The two categories of interventions that reduced all-cause readmissions and mortality (home-visiting programs and MDS-HF clinic interventions) were more likely to include teams of providers delivering the intervention (e.g., home visits that a nurse and pharmacist conducted together) than interventions that did not show efficacy (e.g., telemonitoring, primarily educational interventions). STS interventions (delivered primarily by nurses and pharmacists), were efficacious in reducing mortality but did not reduce all-cause readmissions. Within categories, evidence was insufficient to draw definitive conclusions about whether specific delivery personnel are more or less efficacious for reducing all-cause readmissions or mortality.

Across intervention categories, interventions were primarily delivered face-to-face or via technology (telephone, telemonitoring, video visits). The two categories of interventions delivered primarily face-to-face reduced all-cause readmission—i.e., home-visiting programs and MDS-HF clinic interventions. For these two categories, method of delivery did not vary within each category. STS reduced mortality; some of these interventions included a face-to-face component (e.g., predischarge educational intervention). In general, interventions primarily delivered remotely (i.e., telemonitoring, STS) did not reduce all-cause readmissions. Only STS interventions varied in the method of communication; our subgroup analyses for reduction in all-cause readmissions and mortality found no statistically significant difference by method of communication at any outcome timepoint.

Discussion

For improving our primary outcomes, we found the best evidence of efficacy for home-visiting programs, STS, and MDS-HF clinic interventions. We had very little evidence on whether interventions reduced 30-day readmissions; most studies reported rates over 3 or 6 months. One home-visiting trial showed efficacy in reducing both all-cause readmission and the 30-day combined (all-cause readmission or death) outcome.[32]

The two categories of interventions that reduced all-cause readmissions and the composite outcome (home-visiting programs and MDS-clinic interventions) are multicomponent, complex interventions. We could not separate out individual components from the overall bundle of interventions that showed efficacy; we found no single-component intervention that reduced all-cause readmissions. Few trials reported on whether transitional care interventions increased or decreased ER visits. Furthermore, few trials measured quality of life at the same timepoint with the same scale. No trial assessed whether transitional care interventions increased or decreased caregiver or self-care burden.

Few trials reported readmission rates within 30 days following a HF hospitalization. Whether certain interventions that reduce readmissions at 3 and 6 months would also be effective in reducing earlier readmissions remains uncertain. Data based on Medicare claims suggest that 35.2 percent of 30-day readmissions are for HF; the remainder are for diverse indications (e.g., renal disorders, pneumonia, arrhythmias, and septicemia or shock).[5] We found the best evidence for interventions that provided relatively frequent in-person monitoring following discharge—specifically, home-visiting programs and MDS-HF clinic interventions. Interventions that did not show efficacy for all-cause readmissions tended to focus on HF self-management alone (e.g., STS, primarily educational interventions). For reducing all-cause readmissions, focusing on HF disease management alone does not appear sufficient.

Current clinical practice in the care of adults with HF after hospitalization varies greatly. A recent telephone survey of 100 U.S. hospitals found wide variation in education, discharge processes, care transition, and quality-improvement methods for patients hospitalized with HF.[14] As mentioned in the introduction to this review, readmission rates vary by both geographic location and insurance coverage.[38] Our findings provide some guidance to quality-improvement efforts, which aim to reduce readmissions for people with HF. Specifically, systems or providers aiming to implement interventions to improve transitional care for patients with HF may be uncertain about what type of intervention to implement. Our results suggest that home-visiting programs and MDS-HF clinic interventions currently have the best evidence for reducing all-cause readmissions and should receive the greatest consideration.

Applicability

Most studies included adults with moderate to severe HF. The mean age of subjects was generally in the 70s; very few studies enrolled patients who were, on average, either younger or older. We did not find evidence to confirm or refute whether treatments are more or less efficacious for many other subgroups, including groups defined by sex, racial or ethnic minorities, people with higher severity of HF, and those with certain coexisting conditions. Included trials commonly excluded patients who had end-stage renal disease or severe or unstable cardiovascular disease (e.g., recent myocardial infarction). The interventions included are applicable only to patients who are discharged to home; whether interventions would benefit patients who are discharged to another institution (e.g., assisted living facility) remains unclear.

One of three trials assessing MDS-HF clinic was conducted in the United States; the other two were conducted in Taiwan and Canada. Whether results reflect differences in populations or health care systems is unclear. Approximately one-half of the home-visiting programs were conducted in the United States; the others were conducted in Australia, the United Kingdom, and various European countries. Across most included trials, the majority of patients were prescribed an ACEI or ARB (when information was reported); however, the percentages of patients across trials who were prescribed beta-blockers at discharge varied widely across trials.

Whether "usual care" in trials published during the early 1990s is comparable to current practice is not clear. In general, studies did not report on details of usual care, including whether followup was scheduled soon after discharge or whether patients were receiving additional services such as home health care. Included trials were conducted in a mix of settings; these settings include academic medical centers, VA hospital settings, and community hospitals.

Limitations of the Comparative Effectiveness Review Process

The scope of this review targeted adults hospitalized for HF. We did not evaluate transitional care interventions either for adults hospitalized for other reasons or for children and adolescents.

The interventions in the included trials were heterogeneous and could probably be categorized using a variety of approaches. We classified them in a manner that we believe is both descriptive and informative, but other approaches to categorization could lead analysts to different conclusions. Other reviews have highlighted the difficulty in classifying studies into distinct categories. For example, one trial by Rainville et al.[39] classified as STS in our report and also classified as STS in a 2011 Cochrane review[40] while a 2012 Cochrane review classified the same study as case management, grouping it with trials that assessed a home-visiting program.[41]

We use the term "transitional care" broadly; generally we were guided by Coleman's definition as "a set of actions designed to ensure the coordination and continuity of health care as patients transfer between different locations or different levels of care within the same location" (p. 30).[20] The included interventions are diverse in terms of whether they aimed to coordinate care at the provider level or focused more on strategies to transfer care back to the patient (e.g., through self-care training for HF management). We did not include or exclude studies based on any specific set of components; for that reason, included trials assess diverse interventions. We chose to cast a broad net to include a comprehensive set of strategies to reduce readmissions that would be useful to stakeholders in different settings (hospitals, outpatient clinics, or others).

Our inclusion and exclusion criteria specified that included studies had to enroll patients during (or within 1 week) of a hospitalization for HF and also had to measure a readmission rate before 6 months. We did not include readmission rates or mortality rates measured longer than 6

months; interventions that we did not find efficacious may still be beneficial in long-term disease management in patients with HF (e.g., perhaps for reducing 12-month readmission rates).

Finally, publication bias and selective reporting are potential limitations. Although we searched for unpublished studies and unpublished outcomes, we did not find direct evidence of either of these biases. Many of the included trials were published before trial registries (e.g., clinicaltrials.gov) became available; had we been able to consult such registries, we would have had greater certainty about the potential for either type of bias.

Limitations of the Evidence Base

The evidence base was inadequate to draw conclusions for some of our questions or subquestions of interest. In particular, as described above, direct evidence was insufficient to permit us to draw any conclusions on comparative effectiveness of transitional care interventions. In addition, evidence was quite limited for some outcomes (e.g., readmissions within 30 days, utilization outcomes, and quality of life). Evidence was similarly insufficient to draw any definitive conclusions about whether any transitional care interventions are more or less efficacious in reducing readmissions or mortality based on patient subgroups defined by age, sex, race, ethnicity, socioeconomic status, disease severity, or coexisting conditions. We found just two eligible trials reporting information on different subgroups. We identified little evidence on the potential harms of transitional care interventions, such as whether they increase caregiver burden or increase the rate of ER visits. None of the included trials measured caregiver burden, which is relevant given that health care interventions affect not only the health of the individual receiving the intervention but also the health of those close to the patient.

Many of the included trials had methodological limitations introducing some risk of bias. Some trials did not clearly describe methods used for assessing utilization outcomes (e.g., readmissions, ER visits). Methods of handling missing data varied; some trials did nothing to address missing data (i.e., analyzed only completers). However, many trials conducted true intention-to-treat analyses and used appropriate methods of handling missing data, such as imputing return readmissions for subjects lost to followup.

Limitations also included inadequate sample size and significant heterogeneity of outcome measures across trials (specifically types of readmission rates). Reporting of use of health services other than for the primary outcomes, such as ER visits, was variable across the included studies.

Sometimes usual care and certain aspects of treatment interventions were not adequately described. Specifically, descriptions of whether (and how) interventions addressed medication management were often unsatisfactory. Categories of interventions that showed efficacy (e.g., MDS-HF clinic interventions and home-visiting programs) often included frequent visits with clinicians. Separating out individual components that are necessary from the overall type of interventions that showed efficacy was not possible. Moreover, some confounding components that were not described may be associated with efficacy as well (e.g., addressing social needs, optimizing HF pharmacotherapy).

Research Gaps

We identified important gaps in the evidence that future research could address; many are highlighted above. Of note, these gaps relate only to the key questions addressed by this report, and they should not eliminate a wide range of potentially important research that falls outside the

specified scope of this review. Table C summarizes the gaps and offers examples of potential future research that could address the gaps.

Table C. Evidence gaps for future research, by key question

KQ	Evidence Gap	Potential Future Research
1	Few trials measured 30-day all-cause readmission outcomes (including those rated as high or unclear risk of bias); we found low SOE for home-visiting programs in reducing all-cause readmission and the combined outcome (all-cause readmission or death). Evidence was insufficient to determine the efficacy of other intervention categories in reducing 30-day readmission rates.	Future studies should evaluate whether interventions that show efficacy in reducing 3- and 6-month readmission rates are also effective in reducing 30-day readmission rates (e.g., care in a MDS- HF clinic following discharge). Future trials should ensure that the sample size and method of ascertaining readmission outcomes are adequate to determine the effect of transitional care interventions on 30-day readmission rates.
1, 3-4	Descriptions of key intervention components (content and process) were inconsistently reported across included studies. Some trials provided great detail, others very little. There does not appear to be a common conceptual framework used among researchers who aim to assess whether interventions reduce readmissions for the included timepoints (30 days to 6 months).	Future research of transitional care interventions could rely on guidance from the AHA statement addressing taxonomy for disease management [1] that provides guidance used to categorize and compare disease management programs. Alternatively, this taxonomy could be amended to include more specific guidance on categorizing transitional care type interventions (e.g., incorporate subdomains in the "environment" domain that is more specific to the transition period).
1	Evidence was insufficient to determine the comparative effectiveness of transitional care interventions.	Future RCTs should address whether certain types of interventions are more efficacious than others. For example: (1) home-visiting programs that are higher vs. lower intensity or that differ in specific components (2) MDS- HF clinic followup compared with home visits that provide similar periodicity of followup and content (e.g., education on self-care and medication reconciliation).
1	Telemonitoring interventions did not reduce readmissions over 6 months; whether this can be attributed to lack of care coordination or other factors remains unclear.	Future RCTs of telemonitoring interventions should include factors that appear to be necessary (or add benefit). For example, telemonitoring that starts immediately after discharge, is combined with initial in-person visits (in the clinic or in the home), and is integrated with the patient's established outpatient care.
1,2	Evidence was insufficient to determine whether interventions based in a primary care clinic can reduce readmissions for patients with HF (the one included primary care intervention occurred in a Veterans Administration hospital setting).	Future studies should focus on whether interventions delivered in a primary care setting, featuring components shown to be efficacious (e.g., in-person self-management education and monitoring during home visits or frequent clinic appointments) reduce 30-day readmission rates. These interventions may be more applicable (compared to interventions delivered in a more specialized setting).
2	Evidence was insufficient to determine efficacy of transitional care interventions in reducing 30-day mortality.	Future trials and observational studies should evaluate whether interventions that reduce 30-day readmission rates increase or decrease mortality. Interventions that show efficacy in RCTs may not perform differently under diverse settings. There remains a concern about the relationship between reductions in 30-day readmission rates and mortality, especially for vulnerable populations.
2	Literature does not address the effect of interventions on burdens placed on either patients themselves or their caregivers.	Future research should include validated caregiver burden measures as well as patient-reported measures that address self-care burden and quality of life. Beyond changes in disease-specific outcomes (MLWHFQ), evidence was generally insufficient to determine the effect of interventions on patient reported outcomes.

Table C. Evidence gaps for future research, by key question (continued)

KQ	Evidence Gap	Potential Future Research
5	Evidence was insufficient to determine whether certain subgroups of patients benefit from transitional care interventions.	Future research could assess whether readmission rates differ by disease severity, low-income patients, or patients from racial and ethnic minorities.

Abbreviations: AHA = American Heart Association; KQ = key question; MDS-HF, multidisciplinary heart failure clinic; MLWHFQ = Minnesota Living With Heart Failure Questionnaire; RCT = randomized controlled trial.

Also, we identified several methodological issues that increased the risk of bias for trials measuring readmission rates which could be addressed in future research. Often trials provided inadequate description of the method of ascertaining health care utilization outcomes (e.g., readmissions, ER visits)—specifically whether measurements were based on patient report, chart review or some combination of measurements. There were concerns about masking of outcome assessments; for example, in some trials personnel delivering the intervention also appeared to be primarily responsible for measuring health care utilization. Future studies should consider methods (such as blinded outcome assessments) that guard against measurement bias.

Conclusions

Few trials evaluating transitional care interventions for adults with HF reported 30-day readmission rates; we identified one home-visiting trial that reduced all-cause readmission and the combined endpoint all-cause readmission or death (low SOE). We found the best evidence of efficacy for improving at least one of our primary outcomes over 3 to 6 months for three main approaches: home-visiting programs, STS, and MDS-HF clinic interventions. Specifically, we found that home-visiting programs reduced all-cause readmission rates (30 days, 3 and 6 months), HF-specific readmission rates (3 months), and of the combined endpoint all-cause readmission or death (30 days, 3 and 6 months); that STS interventions reduced HF-specific readmission rates (3 and 6 months) and mortality (6 months); and that MDS-HF clinic interventions reduced all-cause readmission rates and mortality (both over 6 months). The SOE for these conclusions was moderate. For these outcomes, NNTs ranged from 5 to 10 for home-visiting programs, from 10 to 25 for STS interventions, and from 7 to 13 for MDS-HF clinic interventions. Current evidence does not establish the efficacy of telemonitoring interventions or primarily educational interventions for reducing readmissions or mortality. Direct evidence was insufficient to conclude whether one type of intervention was more efficacious than any other type. Evidence was generally insufficient to determine whether the efficacy of interventions differed for subgroups of patients.

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Introduction

Background

Heart failure (HF) is a major clinical and public health problem and a leading cause of hospitalization and health care costs in the United States. It is the most common principal discharge diagnosis among Medicare beneficiaries and the third highest for hospital reimbursements, according to 2005 data from the Centers for Medicare & Medicaid Services (CMS).[2] Up to 25 percent of patients hospitalized with HF are readmitted within 30 days.[3-6] These numbers vary by geographic area and insurance coverage.[7]

Interventions aimed specifically at preventing early readmission among patients with HF have been developed and often referred to as "transitional care interventions."[8,9] To reduce the frequency of rehospitalization of Medicare patients, in October 2012 CMS began lowering reimbursements to hospitals with excessive risk-standardized readmission rates as part of the Hospital Readmissions Reduction Program authorized by the Affordable Care Act.[10] These measures apply to patients readmitted to any hospital within 30 days of discharge for applicable conditions (HF, acute myocardial infarction, and pneumonia). These policies may promote hospitals to develop effective transition programs to reduce readmission rates for people with HF.

An assessment of the effectiveness and harms of transitional care interventions is needed to support evidence-based policy and clinical decisionmaking. Despite advances in the quality of acute and chronic HF disease management, gaps remain in knowledge about effective interventions to support the transition of care for patients with HF.

Epidemiology of Heart Failure in the United States

Nearly 7 million Americans 18 years of age and older were diagnosed with HF in 2010; an additional 3 million Americans will have the condition by 2030.[11,12] The incidence of HF increases with age; it affects 1 of every 100 people after 65 years of age.[13] Coronary disease and uncontrolled hypertension are the highest population-attributable risks for HF.[14] Three-quarters of HF cases have antecedent hypertension. Survival after HF diagnosis has improved over time, as shown by data from the Framingham Heart Study[15] and the Olmsted County Study.[16] However, the death rate remains high: 50 percent of people diagnosed with HF die within 5 years after diagnosis.[15,16] Among Medicare beneficiaries, more than 30 percent of patients with HF die within 1 year after hospitalization.[17] National data show no evidence that readmission rates for HF patients have fallen during the past 2 decades, despite the observation that HF hospitalizations in the United States have declined by almost 30 percent during the past decade.[18]

Heart Failure and Preventable Readmissions

Goldfield and colleagues defined a preventable readmission as one clinically related to the prior admission if there was a reasonable expectation that it could have been prevented by provision of quality care in the initial hospitalization, adequate discharge planning, adequate postdischarge followup, or improved coordination between inpatient and outpatient health care teams.[19] Although hospital readmission within 30 days of discharge is a crude measure, it has long been used as a quality metric.

In 2007, the Medicare Payment Advisory Commission called for hospital-specific public reporting of readmission rates, identifying HF as a priority condition. The Commission stated

that readmissions for HF were common, costly, and often preventable.[20] An estimated 12.5 percent of admissions for HF were potentially preventable; this number is based on claims data analysis that identifies "red flags" in readmission diagnoses that are likely to represent conditions associated with a prior admission (and therefore likely preventable).[21]

Readmissions following an index hospitalization for HF appear to be related to various conditions. An analysis of 2007 to 2009 Medicare claims data showed that 24.8 percent of beneficiaries admitted with HF were readmitted within 30 days; 35.2 percent of those readmissions were for HF, and the remainder of readmissions were for diverse indications (e.g., renal disorders, pneumonia, arrhythmias, and septicemia/shock).[6] The broad range of conditions responsible for readmissions may reflect a "posthospitalization syndrome"—a generalized vulnerability to illness among recently discharged patients.[6,22]

The relationship between readmission rates and other important outcomes (e.g., mortality, emergency room visits) is unclear. Some data suggest that hospitals with the lowest mortality rate among patients with HF tend to have higher readmission rates.[23]

Transitional Care for People with Heart Failure

Poorly executed care transitions can lead to inappropriate use of hospital, emergency care, and other services. Recently, experts have used the phrase *transitional care interventions* to describe disease-management interventions targeted toward populations transitioning from one care setting to another. Naylor and colleagues defined transitional care as "a broad range of time-limited services designed to ensure health care continuity, avoid preventable poor outcomes among at-risk populations, and promote the safe and timely transfer of patients from one level of care to another or from one type of setting to another" (p.747).[8] Transitional care interventions overlap with other forms of care (primary care, care coordination, discharge planning, disease management and case-management); however, they aim specifically to avoid poor clinical outcomes arising from uncoordinated care.[24] Similarly, the American Geriatrics Society defines transitional care as "a set of actions designed to ensure the coordination and continuity of health care as patients transfer between different locations or different levels of care within the same location" (p. 30).[24] Interventions include logistical arrangements, education of the patient and family, and coordination among the health professionals involved in the transition.

No clear consensus exists about when the transition period ends. Although evaluating 30-day readmissions is important for certain stakeholders (hospitals, payers, quality improvement organizations), outcomes beyond this period are clinically important and may benefit from overall improvements in care. Outcomes far away from the index hospitalization probably reflect the natural history of HF or an unrelated illness, rather than a preventable readmission related to the transition of care. No clear recipe or set of intervention components defines transitional care interventions; changes at the patient clinician, facility, and, and system levels are emphasized throughout the care transition. Transitional care interventions tend to focus on the following: patient or caregiver education (including education on self-management, e.g., self-titrating diuretics), medication reconciliation, coordination with outpatient providers, arrangements for future care (e.g., home health, outpatient followup), and symptom monitoring or reinforcement of education during the transition (e.g., home visits, telephone support, or additional outpatient visits).

Existing Guidelines and Current Practice

Existing Guidelines

The 2013 American Heart Association/American College of Cardiology (AHA/ACC) Heart Failure guidelines addressed postdischarge HF interventions.[25] These guidelines focus on the importance of optimizing HF pharmacotherapy prior to discharge, providing HF education prior to discharge (including self-care), and addressing barriers to care among other factors. Specifically, the following components were noted as reasonable care options: a follow-up visit within 7 to 14 days of disease and/or a telephone followup within 3 days of discharge.[25] The AHA/ACC guidelines also recommend initiating multidisciplinary HF disease management programs for patients at high risk for readmission. The 2010 Heart Failure Society of America guidelines are similar; their guidance emphasizes particular components of discharge planning.[22] No specific guidance is given on the optimal components of transitional care interventions aimed at preventing readmissions for patients with HF.

Current Practice

Several national performance measures pertain to the standard of care for hospital discharge of HF patients. The Joint Commission performance measures mandate that all patients with HF should receive comprehensive written discharge instructions or other educational materials that address activity level, diet, discharge medications, follow-up appointment, weight monitoring, and planned actions to take should symptoms worsen.[26] These measures are publicly reported by hospitals. In 2011, the ACC/AHA/AMA (American Medical Association) Performance Consortium added a documented postdischarge appointment to the list of recommended HF performance measures.[27] Required documentation includes location, date, and time for a follow-up office visit or home health care visit.

Current clinical practice in the care of adults with HF after hospitalization is quite diverse. A recent telephone survey of 100 U.S. hospitals found wide variation in education, discharge processes, care transition, and quality-improvement methods for patients hospitalized with HF.[18] Readmission rates vary by both geographic location and insurance coverage.[7]

Rationale for Evidence Review

Targeting preventable readmissions is an important goal in reducing overall health care costs from both societal and payer perspectives. The cost of care in HF patients is growing as the population ages; the predominant cost driver is hospitalization. Readmissions account for an estimated $15 billion in annual Medicare spending.[28] For hospitals, reducing 30-day risk-stratified readmission rates may prevent a reduction in Medicare reimbursement. From a patient perspective, addressing preventable readmissions may improve quality of life or function, reduce personal costs, and lower caregiver burden. However, uncertainty remains about effective strategies to reduce early readmission rates among adults with HF. Recent systematic reviews that have addressed HF disease management or transitional care programs have tended to focus on outcomes at 6 to 12 months after an index hospitalization,[29] include a narrow range of interventions,[30] or exclude interventions that are disease specific (i.e., specific to HF patients).[31] Potential harms or unintended consequences of interventions do not appear to have been widely considered in previous reviews. For example, HF may place a tremendous burden on patients and families. Effective self-care involves adhering to medication regimens, observing dietary

restrictions, managing symptom (e.g., adjusting diuretic dosing) and notifying providers when problems arise.[32,33] Interventions aimed to improve self-care among HF patients may increase patient and caregiver burden.

Scope and Key Questions

A community hospital administrator nominated this topic; the nominator wanted to know how to prevent readmissions for patients with HF. The primary interest involved the Hospital Readmissions Reduction Program and penalties assigned by CMS for excess risk-stratified readmissions. The nominator commented that reducing mortality and improving quality of life were also important outcomes.

To address these issues, we conducted a systematic review and meta-analysis of the effectiveness of transitional care interventions for adults with HF. Our report focuses mainly on transitional care interventions that aim to reduce early readmissions and mortality for patients hospitalized with HF; we also examine several related issues, including potential harms of such interventions. Specifically, we address the following five Key Questions (KQs):

Key Question 1

Among adults who have been admitted for heart failure, do transitional care interventions increase or decrease the following health care utilization rates:

a. Readmission rates
b. Emergency room visits
c. Acute care visits
d. Hospital days (of subsequent readmissions)?

Key Question 2

Among adults who have been admitted for heart failure, do transitional care interventions increase or decrease the following health and social outcomes:

a. Mortality rate
b. Functional status
c. Quality of life
d. Caregiver burden
e. Self-care burden?

Key Question 3

This question has three parts:

a. What are the components of effective interventions?
b. Among effective interventions, are particular components necessary?
d. Among multicomponent interventions, do particular components add benefit?

Key Question 4

This question has three parts:

a. Does the effectiveness of interventions differ based on intensity (e.g., duration, frequency or periodicity) of the interventions?
b. Does the effectiveness of interventions differ based on delivery personnel (e.g., nurse, pharmacist)?
c. Does the effectiveness of interventions differ based on method of communication (e.g., face-to-face, telephone, Internet)?

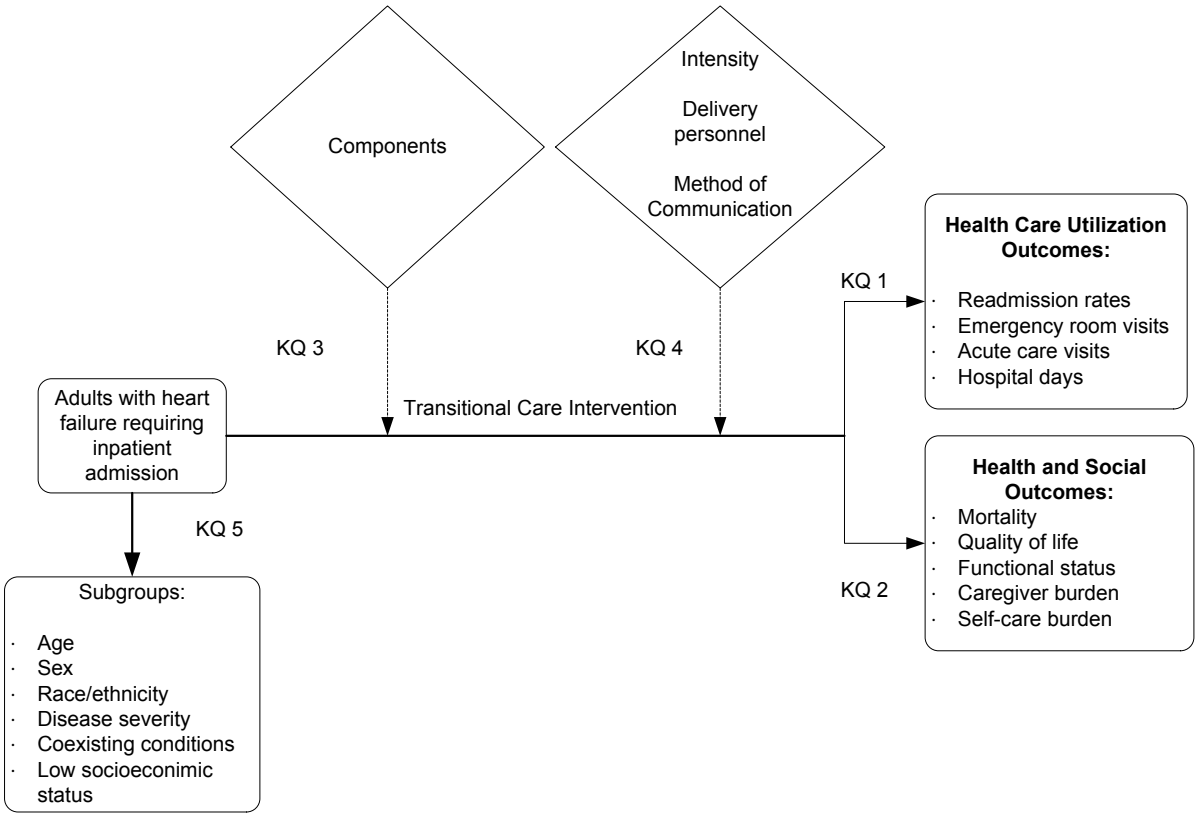
Key Question 5

Do transitional care interventions differ in effectiveness or harms for subgroups of patients based on age, sex, race, ethnicity, disease severity (left ventricular ejection fraction or New York Heart Association classification), coexisting conditions, or socioeconomic status?

Analytic Framework

We developed an analytic framework to guide the systematic review process (Figure 1). It notes all five KQs. Both KQ 1 and KQ 2 address the potential benefits and harms of transitional care interventions.

Figure 1. Analytic framework for transitional care interventions to prevent readmissions in people with heart failure



Abbreviation: KQ = key question

Organization of This Report

The remainder of the review describes our methods in detail and presents the results of our synthesis of the literature with summary tables and the strength-of-evidence grades for major comparisons and outcomes. The discussion section offers our conclusions, summarizes our findings, and provides other information relevant to the interpretation of this work for clinical practice and future research. References, a list of acronyms and abbreviations, and a glossary of terms follow the Discussion section.

Appendix A contains the exact search strings we used in our literature searches. Studies excluded at the stage of reviewing full-text articles with reasons for exclusion are presented in Appendix B. Detailed tables of intervention components appear in Appendix C. Appendix D provides the specific questions used for evaluating the risk of bias of all included studies, documents risk-of-bias ratings for each study, and explains the rational for high or unclear ratings. Appendices E and F document various meta-analyses (Appendix E gives forest plots to summarize results of individual studies and pooled analyses; Appendix F presents sensitivity analyses). Appendix G presents information about our grading of the strength of the various bodies of evidence (tables for individual domain assessments and overall strength-of-evidence grades for each KQ, organized by intervention category).

Methods

The methods for this review follow those specified for the Agency for Healthcare Research and Quality (AHRQ) Evidence-based Practice Center (EPC program. This guidance is codified in *Methods Guide for Effectiveness and Comparative Effectiveness Reviews* (hereafter, *Methods Guide*, available at http://www.effectivehealthcare.ahrq.gov/methodsguide.cfm).

Topic Refinement and Review Protocol

During the topic development and refinement processes, we engaged in a public process to develop a draft and final protocol for the systematic review process. We generated an analytic framework, preliminary Key Questions (KQs), and preliminary inclusion/exclusion criteria in the form of PICOTS (populations, interventions, comparators, outcomes, timing, settings). The processes were guided by the information provided by the topic nominator, a scan of the literature, methods and content experts, and Key Informants. We worked with six Key Informants during the topic refinement, three of whom were subsequently members of our Technical Expert Panel (TEP) for this report. Key Informants and a total of eight TEP members participated in conference calls and discussions through email to review the analytic framework, KQs, and PICOTS, discuss the preliminary assessment of the literature, provide input on the information and categories included in evidence tables, and comment on the data analysis plan.

Our KQs were posted for public comment on AHRQ's Effective Health Care Web site from February 22, 2013, through March 21, 2013; we revised them as needed after review of the comments and discussion with AHRQ and the TEP, primarily for clarity and readability. We then drafted a protocol, which was also posted on the Effective Health Care Web site on June 10, 2013.

Literature Search Strategy

Search Strategy

We searched MEDLINE®, the Cochrane Library, and the Cumulative Index to Nursing and Allied Health Literature (CINAHL)® from July 1, 2007 to May 9, 2013. We also used a previous AHRQ Technology Assessment on a similar topic to identify randomized controlled trials (RCTs) published before 2007.[34] The full search strategy is presented in Appendix A.

We used either Medical Subject Headings (MeSH) or major headings as search terms when available or key words when appropriate, focusing on terms to describe the relevant population and interventions of interest. We reviewed our search strategy with the TEP and incorporated their input into our search strategy. An experienced information scientist (an EPC librarian) conducted the searches and another information scientist at the EPC peer-reviewed them. We conducted quality checks to ensure that our searches identified known studies (i.e., studies identified during topic nomination and refinement).

Using the previously published AHRQ Technology Assessment on Non-Pharmacological Interventions for Postdischarge Care in Heart Failure, we identified relevant studies published from1990 through 2006 to 2007.[34] Its start date (1990) reflects the timing of advances in the medical management of heart failure (HF), including the increased use of beta-blockers. We applied our current inclusion and exclusion criteria to RCTs in this earlier publication; our criteria are similar but narrower in scope—that is, limited to outcomes (readmissions, deaths, or other outcomes) timings occurring no more than 6 months from the index hospitalization.

We also searched MEDLINE, the Cochrane Library, and CINAHL for nonrandomized trials or prospective cohort studies of transitional care interventions that measured caregiver or self-care burden from 1990 to May 5, 2013. The previous review did not include these outcomes. We included observational studies to ensure that we captured relevant literature addressing these potential consequences of transitional care interventions that RCTs may be less likely to report.

We searched for unpublished studies relevant to this review using ClinicalTrials.gov and the World Health Organization's International Clinical Trials Registry Platform.

We manually searched reference lists of pertinent reviews, included trials, and background articles on this topic to look for any relevant citations that our searches might have missed. We imported all citations into an EndNote® X4 electronic database.

We will conduct an updated literature search (of the same databases searched initially) concurrent with the peer-review process. Any literature suggested by peer reviewers or public comment respondents will be investigated and, if found appropriate, incorporated into the final review. Appropriateness will be determined by the same methods (inclusion and exclusion criteria) listed below (Table 1).

Inclusion and Exclusion Criteria

We developed eligibility (inclusion and exclusion) criteria with respect to PICOTS, study designs, and study durations for each KQ (Study Selection

Two trained members of the research team independently reviewed all titles and abstracts (identified through searches) for eligibility against our inclusion/exclusion criteria. Studies marked for possible inclusion by either reviewer underwent a full-text review. For titles and abstracts that lacked adequate information to determine inclusion or exclusion, we retrieved the full text and reviewed it.

Two trained members of the research team independently reviewed each full-text article for inclusion or exclusion based on the eligibility criteria (Table 1). If both reviewers agreed that a study did not meet the eligibility criteria, we excluded it. If the reviewers disagreed, they resolved conflicts by discussion and consensus or by consulting a third senior member of the review team.

All results in both review stages were tracked in an EndNote® database. We recorded the principal reason that each excluded full-text publication did not satisfy the eligibility criteria (Appendix B).

Table 1). The focus of this review is on the primary outcomes of readmission rates and mortality. We also evaluated the following outcomes when studies assessing readmission rates or mortality reported them: emergency room visits, acute care visits, hospital days (of subsequent readmissions), quality of life, functional status, caregiver or self-care burden. We were specifically interested in validated measures of caregiver outcomes and outcomes specific to patient self-care burden. We cast a broad net and initially included any outcomes that might be relevant in both RCTs and observational studies. During full-text review, we specifically excluded outcomes that measured patient satisfaction and self-care knowledge.

Study Selection

Two trained members of the research team independently reviewed all titles and abstracts (identified through searches) for eligibility against our inclusion/exclusion criteria. Studies marked for possible inclusion by either reviewer underwent a full-text review. For titles and abstracts that lacked adequate information to determine inclusion or exclusion, we retrieved the full text and reviewed it.

Two trained members of the research team independently reviewed each full-text article for inclusion or exclusion based on the eligibility criteria (Table 1). If both reviewers agreed that a study did not meet the eligibility criteria, we excluded it. If the reviewers disagreed, they resolved conflicts by discussion and consensus or by consulting a third senior member of the review team.

All results in both review stages were tracked in an EndNote® database. We recorded the principal reason that each excluded full-text publication did not satisfy the eligibility criteria (Appendix B).

Table 1. Inclusion/exclusion criteria for studies of transitional care interventions for patients hospitalized for heart failure

Category	Criteria	
	Inclusion	**Exclusion**
Population	• Adults (ages 18 years or older) with HF requiring inpatient admission • Recruited during hospitalization or within 1 week of the index hospitalization	Children and adolescents under 18
Interventions	Any transitional care interventions aimed at reducing readmissions, including one or more of the following components: • Education to patient or caregiver (or both), delivered pre- or postdischarge (or both) • Discharge planning • Appointment scheduling before discharge • Increased planned or scheduled outpatient clinic visits (primary care, multidisciplinary HF) • Home visits • Telemonitoring (including remote clinical visits) • Telephone support • Transition coach or case management • Interventions to increase provider continuity (same provider-continuity between inpatient and outpatient care)	• proBNP guided therapy • Pharmacotherapy (e.g., randomized trials of using a medication compared with placebo) • Physician training (e.g., continuing medical education on evidence-based treatment for HF patient management) • Surgical interventions or invasive procedures (e.g., left ventricular assist device, ultrafiltration, dialysis) • Technology aimed at guiding evaluation of patient volume status (e.g., pulmonary artery pressure sensor, segmental multifrequency bioelectrical impedance analysis)
Comparators	• Usual care, routine care, or standard care (as defined by the primary studies) • Comparison of one intervention with another eligible intervention	Comparison of one intervention with an excluded intervention.
Outcomes[a]	KQ 1 : Readmission rates, emergency room visits, acute care visits, all-cause hospital days (of subsequent readmissions) KQ 2: Mortality, quality of life, functional status,[b] caregiver or self-care burden KQ 3: All-cause readmissions, mortality and combined all-cause readmission or death KQ 4: All-cause readmission and mortality KQ 5. Subgroups: any outcome eligible for KQ 1 or KQ 2	Trials that reported only an eligible quality-of-life or functional status outcome (and no readmission or mortality rate) were excluded from the analysis unless they were a companion to a trial that measured readmission rates.
Timing of outcome measurement Length of followup	• Outcomes (readmissions, deaths, or other outcomes) occurring no more than 6 months from the index hospitalization • Followup must be at least 30 days	• Outcomes measured at any time after 6 months • Followup is less than 30 days
Time period	Studies published from 1990 to the present	Studies published earlier than 1990.
Settings	• Interventions occurring during the index hospitalization, before discharge • Interventions initiated as an outpatient following the index hospitalization • Interventions bridging the transition from inpatient to outpatient care	All other settings (e.g., discharge to a skilled nursing facility or rehabilitation center)
Publication language	English	All other languages

Table 1. Inclusion/exclusion criteria for studies of transitional care interventions for patients hospitalized for heart failure (continued)

Category	Criteria	
	Inclusion	Exclusion
Admissible evidence (study design and other criteria)	• Original research • Eligible study designs include the following: – For all KQs, randomized controlled trials – For caregiver burden and self-care burden, nonrandomized controlled trials or prospective cohort studies with an eligible comparison group	• Case series • Case reports • Nonsystematic reviews • Systematic reviews • Editorials • Letters to the editor • Case-control studies • Retrospective cohort studies • Studies with historical, rather than concurrent, control groups

[a] We did not consider results presented only in figures (e.g., Kaplan-Meier curves) as eligible for inclusion when results were not clearly reported for an eligible outcome timing (readmission rate no more than 6 months from the index hospitalization).

[b] Eligible quality of life and functional status measures included the Minnesota Living With Heart Failure Questionnaire (MLWHFQ), the Quality of Life Index – Cardiac Version, Kansas City Heart Failure Questionnaire, 6-minute walk test, change in the New York Heart Association (NYHA) classification from baseline, Medical Outcomes Study Short Form with 36 items (SF-36), 12-Item Short form Health Survey (SF-12) and EuroQoL (or EQ-5D).

Abbreviations: HF = heart failure; KQ = Key Question; proBNP = probrain natriuretic peptide; PICOTS = populations, interventions, comparators, outcomes, timing, and setting.

Data Extraction

For studies that met our inclusion criteria, we designed and used structured data extraction forms to gather pertinent information from each article, including characteristics of study populations, settings, interventions, comparators, study designs, methods, and results. Trained reviewers extracted the relevant data from each included article; all data abstractions were reviewed for completeness and accuracy by a second member of the team. We recorded intention-to-treat (ITT) results if available. All data abstraction was performed using Microsoft Excel® software.

Risk-of-Bias Assessment of Individual Studies

To assess the risk of bias (internal validity) of studies, we used predefined criteria based on the AHRQ *Methods Guide*. These included questions to assess selection bias, confounding, performance bias, detection bias, and attrition bias (i.e., those about adequacy of randomization, allocation concealment, similarity of groups at baseline, masking, attrition, whether ITT analysis was used, method of handling dropouts and missing data, reliability and validity of outcome measures, and treatment fidelity).[35] Appendix D provides the specific questions used for evaluating the risk of bias of all included studies. It also includes a table showing the responses to these questions and risk-of-bias ratings for each study and then an explanation of the rationale for all ratings that were either high or unclear. In general terms, results from a low risk-of-bias study are considered to be valid. A study with moderate risk of bias is susceptible to some risk of bias but probably not enough to invalidate its results. A study assessed as high risk of bias has significant risk of bias (e.g., stemming from serious errors in design, conduct, or analysis) that may invalidate its results. We determined the risk-of-bias rating via appraisal of responses to all questions assessing the various types of bias listed above.

We gave high risk-of-bias ratings to studies that we determined to have a fatal flaw (defined as a methodological shortcoming that leads to a very high risk of bias) in one or more categories based on our qualitative assessment. Common methodologic shortcomings contributing to high risk-of-bias ratings were high rates of attrition or differential attrition, inadequate methods used to handle missing data, lack of ITT analysis, and unclear or invalid measures of readmission or mortality rates. We rated studies as unclear risk of bias when information provided was inadequate for judging the validity of outcome measures (primarily readmission rates and mortality).

Two independent reviewers assessed the risk of bias for each study; one of the two reviewers was always an experienced EPC investigator. Disagreements between the two reviewers were resolved by discussion and consensus or by consulting a third member of the team.

We did not use studies deemed high or unclear risk of bias in our main analyses; we included them only in sensitivity analyses. These studies are represented in the counts of included studies.

Categorization of Interventions

After reviewing studies that met our inclusion and exclusion criteria, we grouped studies of similar interventions for our evidence synthesis. The American Heart Association provides a taxonomy of disease management that specifies eight domains: patient population, intervention recipient, intervention content, delivery personnel, method of communication, intensity and complexity, environment, and clinical outcomes.[1] We applied this taxonomy in categorizing intervention types based primarily on the mode and environment of delivery (Table 2). We felt this method of categorization would best address the needs of multiple stakeholders who may be interested in interventions that could be implemented in specific health care settings. Most of the studies included components delivered both during hospitalization and after discharge. We did not use timing of intervention delivery as a primary categorization scheme, but we did abstract detailed information regarding the timing of intervention components in relationship to the index hospitalization. Appendix C provides more information on components of interventions.

Table 2. Categories and definitions of transitional care interventions

Category	Definition
Home-visiting programs	Home visits by clinicians such as a nurse or pharmacist who deliver education, reinforce self-care instructions, perform physical examination, or provide other care (e.g., physical therapy, medication reconciliation). These interventions are often referred to as nurse case management interventions but also can include home visits by a pharmacist or multidisciplinary team.
Structured telephone support	Monitoring, education, and/or self-care management using simple telephone technology after discharge in a structured format (e.g., series of scheduled calls with a specific goal, structured questioning, or use of decision support software).
Telemonitoring	Remote monitoring of physiological data (e.g., electrocardiogram, blood pressure, weight, pulse oximetry, respiratory rate) with digital, broadband, satellite, wireless, or Bluetooth transmission to a monitoring center, with or without remote clinical visits (e.g., video monitoring).
Outpatient clinic-based interventions	Services provided in one of several different types of outpatient clinics—multidisciplinary HF, nurse-led HF, or primary care clinic. The clinic-based intervention can be managed by a nurse or other provider and may also offer unstructured telephone support (e.g., patient hotline) outside clinic hours.
Primarily educational interventions	Patient education (and self-care training) delivered predischarge or upon discharge by various delivery personnel or by modes of delivery: in-person, interactive CD-ROM, video education. Interventions in this category do not feature telemonitoring, home visiting, or structured telephone support; they are not delivered primarily through a clinic-based intervention (described above). Follow-up telephone calls may occur to ascertain outcomes (e.g., readmission rates) but not for monitoring.

Table 2. Categories and definitions of transitional care interventions (continued)

Category	Definition
Other	Unique interventions or interventions that did not fit into any of the other categories (e.g., individual peer support for HF patients).

Abbreviations: CD-ROM = Compact Disc Read-Only Memory; HF = heart failure.

Data Synthesis

We conducted quantitative synthesis using meta-analyses of outcomes reported by multiple studies that were homogeneous enough to justify combining their results. To determine whether meta-analyses were appropriate, we assessed the clinical and methodological heterogeneity of the studies under consideration following established guidance.[36] We did this by qualitatively assessing the PICOTS of the included studies, looking for similarities and differences. When quantitative synthesis was not appropriate (e.g., because of clinical heterogeneity, insufficient numbers of similar studies, or insufficiency or variation in outcome reporting), we synthesized the data qualitatively.

We found sufficient data from RCTs to conduct meta-analyses for some comparisons of interest for the following outcomes: readmission rates (all-cause, HF-specific), combined all-cause readmission or death (composite outcome), mortality, all-cause hospital days and some quality-of-life measures. For all readmission rates, we distinguished measures of people readmitted versus total readmissions per group. We ran meta-analyses of studies that reported the number of people readmitted in each group. When the only information available was on the total number of readmissions (and not total people readmitted), we contacted authors requesting additional data. When we could not obtain information on the number of persons readmitted, we did not include these studies in meta-analyses for number of people readmitted; instead, we included these results in a qualitative synthesis.

We used random-effects models with the inverse-variance weighted method to estimate pooled effects.[37] For binary outcomes (e.g., readmission rates, mortality), we calculated risk differences between groups. For continuous outcomes (e.g., scales of quality of life or function) measured with the same scale (e.g., Minnesota Living With Heart Failure Questionnaire [MLWHF]), we report the weighted mean difference between intervention and control subjects. When multiple scales were combined in one meta-analysis, we used the standardized mean difference (SMD), Cohen's d. We calculated rates using the number of all randomized patients as the denominator to reflect a true ITT analysis when appropriate. Forest plots graphically summarize results of individual studies and of the pooled analyses (Appendix E).

For analyses of the efficacy of transitional care interventions, our main analyses include studies comparing an intervention with usual care (or treatment as usual) control groups. In some cases, "usual care" refers to usual home health care (e.g., home-visiting program); when this was a co-intervention, we included it along with usual care in our analysis but noted this as a footnote to the forest plot. We stratified analyses for each intervention category by timing—to provide pooled point estimates for interventions at different time points following an index hospitalization. When a study reported mortality or readmission rate at 2 months (but not 3 months), we combined the results with studies reporting a 3 month outcome measure.

For KQ 4, we assessed whether the efficacy of interventions differ based on intensity, delivery personnel and method of communication both across intervention categories and also within categories of interventions. We conducted meta-analysis stratified by intensity, delivery personnel and method of communication within each intervention category when appropriate (e.g., when variation existed). Given the heterogeneity of included interventions, we were unable

to develop a single measure of intensity that could be applied to all interventions. For most interventions, we defined intensity as the duration, frequency, or periodicity of patient contact, categorizing each intervention as low, medium or high intensity. We also considered resource use as a dimension of intensity. For example, we included factors such as the total number of intervention components in the determination of intensity. We reserved the low-intensity category for interventions that included one episode of patient contact or that required few resources (e.g., no additional components, such as time spent coordinating care). We considered the majority of interventions to be medium or high intensity; most were multicomponent and included repeated patient contacts. Few studies reported readmission rates separately by patient subgroups; therefore, we were unable to conduct a meta-analysis and we present this information qualitatively.

For each meta-analysis in KQ 1 and KQ 2, we conducted sensitivity analyses by adding studies excluded for having high or unclear risk of bias and calculated a pooled effect to determine whether including such studies would have changed conclusions. Sensitivity analyses are included in Appendix F; these are mentioned in the results only when they changed the overall results. We did not conduct sensitivity analyses for the subgroup comparisons in KQ 4 (intensity, delivery personnel and method-of-communication).

We calculated the chi-squared statistic and the I^2 statistic (the proportion of variation in study estimates due to heterogeneity) to assess statistical heterogeneity in effects between studies.[38,39] An I^2 from 0 to 40 percent might not be important, 30 percent to 60 percent may represent moderate heterogeneity, 50 percent to 90 percent may represent substantial heterogeneity, and ≥75 percent represents considerable heterogeneity.[38] The importance of the observed value of I^2 depends on the magnitude and direction of effects and on the strength of evidence (SOE) for heterogeneity (e.g., p value from the chi-squared test, or a confidence interval for I^2). Whenever we include a meta-analysis with considerable statistical heterogeneity in this report, we provide an explanation for doing so, considering the magnitude and direction of effects.[38] Meta-analyses were conducted using Stata® version 11.1 (StataCorp LP, College Station, TX).

KQ 3 primarily asks "What are the components of effective interventions?" and "Are particular components necessary?" To address this question, we first extracted detailed information on intervention components, focusing on content (e.g., specific educational content) and process (e.g., timing of first home visit following discharge), based on previous literature suggesting important components in HF treatment and transitional care.[24,31,34] We describe common components and combinations of components of interventions that were effective in reducing all-cause readmissions, mortality or the combined end-point all-cause readmission or death.

For KQ 3, we defined effective interventions as: (1) intervention categories (defined in Table 2 in Methods) that reduced all-cause readmissions (from our meta-analyses for KQ 1) or the combined endpoint of all-cause readmission or death; (2) intervention categories that reduced mortality in in our meta-analyses; (3) individual trials in other categories that were efficacious for reducing all-cause readmissions, mortality, or the combined endpoint. Few studies reported outcomes at 30 days; below we describe the components of interventions that showed efficacy at any eligible time point (up to 6 months following an index hospitalization for HF). We focused on all-cause readmissions (rather than HF-readmission rates) for two reasons: (1) this outcome is relevant to stakeholders who are seeking to develop programs that reduce readmission rates in the context of CMS's decision to reduce reimbursement for excessive risk-standardized readmission rates[10] and (2) the majority of early readmissions in HF patients are for diverse

indications (e.g., renal disorders, pneumonia, arrhythmias, and septicemia/shock).[6] We also include mortality as an outcome for two reasons: (1) there is uncertainty about the proportion of readmissions that are preventable and (2) considering improved mortality as an outcome acknowledges the fact that some readmissions are warranted.

Strength of the Body of Evidence

We graded the SOE to answer KQs on the benefits and harms of the interventions in this review, using the guidance established for the EPC program.[40] Developed to grade the overall strength of a body of evidence, this approach incorporates four key domains: risk of bias (includes study design and aggregate quality), consistency, directness, and precision of the evidence. It also considers other optional domains that may be relevant for some scenarios, such as a dose-response association, plausible confounding that would decrease the observed effect, strength of association (magnitude of effect), and publication bias. Table 3 describes the grades of evidence that we assigned.

Table 3. Definitions of the grades of overall strength of evidence

Grade	Definition
High	**High confidence that the evidence reflects the true effect.** Further research is very unlikely to change our confidence in the estimate of effect.
Moderate	**Moderate confidence that the evidence reflects the true effect.** Further research may change our confidence in the estimate of the effect and may change the estimate.
Low	**Low confidence that the evidence reflects the true effect.** Further research is likely to change our confidence in the estimate of the effect and is likely to change the estimate.
Insufficient	**Evidence either is unavailable or does not permit estimation of an effect.**

Source: Owens et al.[40]

Two reviewers assessed each domain for each key outcome and resolved differences by consensus. For each assessment, one of the two reviewers was always an experienced EPC investigator. To give high SOE grades, we required consistent, direct, and precise evidence from studies with aggregate low risk of bias. An unfavorable assessment for any one of the four key domains (e.g., inconsistency, indirectness, imprecision, or medium aggregate risk of bias) typically resulted in downgrading to moderate SOE. Two unfavorable assessments typically resulted in downgrading to low SOE. We allowed reviewers to include the optional domains listed above (e.g., dose-response association, publication bias) if relevant, and to upgrade or downgrade the SOE for those domains if appropriate. When only one study reported an outcome of interest (with unknown consistency and imprecision), we usually graded the SOE as insufficient; when similar interventions had consistent results at other timepoints we graded the SOE as low. We graded SOE for the following outcomes: all-cause readmissions rate, HF-specific readmission rates, combined all-cause readmission or death (composite outcome), mortality, emergency room visits, length of hospital stay (of subsequent readmissions), and commonly reported measures of quality of life or functional status. We graded the SOE separately for each for time-points following an index hospitalization. For readmission rates, we graded the evidence for rates that were specific to the number of people readmitted (not total number of readmissions per group); however, we considered outcome measures of total readmission per group when assessing the consistency of evidence. We did not grade the SOE for results specific to KQ 3 (components of effective interventions), KQ 4 (intensity, delivery personnel, method of communication) or KQ 5 (subgroups). Appendix G presents tables showing

our assessments for each domain and the resulting SOE grades for each KQ, organized by intervention category.

Applicability

We assessed applicability of the evidence following guidance from the *Methods Guide.*[41] We used the PICOTS framework to explore factors that affect applicability. Some factors identified a priori that may limit the applicability of evidence include the following: age of enrolled populations; sex of enrolled populations; race or ethnicity of enrolled populations; few studies enrolling subjects who are uninsured or lack social support; and setting (trials conducted outside the United States).

Peer Review and Public Commentary

This draft report will receive external peer review and be posted for public comment. We will address all comments in the final report, and a disposition of comments report will be publicly posted 3 months after release of the final report.

Results

This chapter begins with the results of our literature search and a general description of the included studies. It is then organized by Key Question (KQ) and grouped by transitional care intervention, in the categories defined in Table 2 (in Methods). A table of intervention components organized by intervention category can be found in Appendix C.

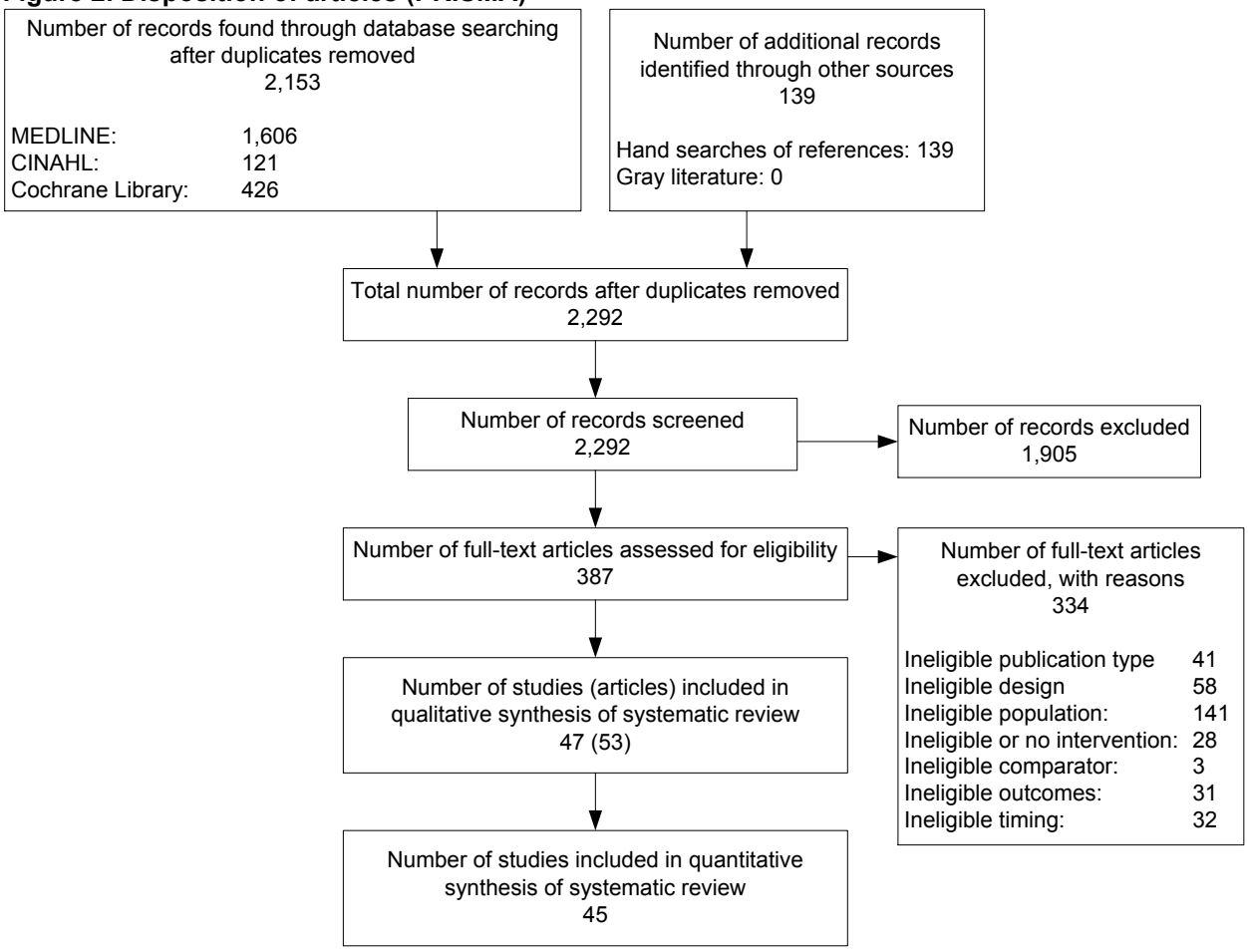
After describing included studies, we present results by KQ. For each KQ, we give the key points, including the strength-of-evidence (SOE) grades, and then present a more detailed synthesis of the literature. (Appendix D includes the risk-of-bias assessment for all included studies, organized by intervention category.).

In the remainder of this chapter, we present the results of interventions compared with usual care first, followed by studies comparing one transitional care intervention with another type of intervention. In the text, results are typically reported as risk differences (RD), relative risks (RR), or hazard ratios (HR) with 95% confidence intervals (CI). Tables in this chapter describing studies (Tables 4–9) are organized first in chronological order by year of publication and, when necessary for more than one study in a year, alphabetically by author. Generally, in text, we present figures with meta-analyses for our primary outcomes (readmission rates and mortality). Other meta-analyses are presented in Appendix E (e.g., hospital days, quality of life) or Appendix F (sensitivity analyses).

Literature Search and Screening

Searches of all sources identified a total of 2,292 potentially relevant citations. We included 47 studies described in 53 publications. Figure 2 describes the flow of literature through the screening process according to PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) categories.[42] Appendix B provides a complete list of articles excluded at the full-text screening stage, with reasons for exclusion. Only randomized controlled trials (RCTs) met the inclusion/exclusion criteria specified in Table 1 (Methods).

Figure 2. Disposition of articles (PRISMA)



Characteristics of Included Studies

We grouped trials of similar interventions based primarily on the mode and environment of delivery as described in Methods (Table 2): home-visiting programs (15 RCTs), structured telephone support (13 trials), telemonitoring (8 trials), outpatient clinic-based interventions (7 trials), and primarily educational interventions (4 trials). We also included two unique interventions in an "other" category; one features "individual peer support" and one emphasizes cognitive training for patients with coexisting mild cognitive impairment.

Most trials compared a transitional care intervention with usual care; only two directly compared more than one transitional care intervention. Usual care was somewhat heterogeneous across trials and often not well described. In all tables, the timing for outcome measurement(s)—readmissions, deaths, or other outcomes—reflects a period of 6 months or less (i.e., meeting our inclusion criteria noted in Table 1 in Methods); some trials may have measured readmissions and other outcomes beyond 6 months. Below we describe the characteristics of included studies by intervention category.

Home-visiting Programs

Characteristics of Trials

We included 14 RCTs comparing a home-visiting program with usual care,[43-56] and one trial comparing a home-visiting program with telemonitoring (Table 4).[57] Sample size ranged from 58 to 339. Only one trial reported a readmission rate at 30 days.[43]

We rated all but five trials as medium or low risk of bias. We rated three trials as high risk of bias and two as unclear risk of bias;[44,45,48,57] the primary problems were high risk of selection bias, measurement bias (readmission rates), and inadequate handling of missing data.

Table 4. Characteristics of trials assessing home-visiting programs

Author, Year Risk of Bias	Intervention Category(N), Comparator (N)	Timing (ms)[a]	Baseline NYHA Class; Mean EF	Age (y)	Female (%)	Non-white (%)	Taking BB or ACEI at discharge (%)	Co-occurring Condition(s) (%)	Setting
Rich et al., 1993[54] US; single institution	Home-visiting program (63), Usual care (35)	3	NYHA mean: 2.8	79	59	50	NR	DM: 31 MI: 23	Med
Rich et al., 1995[53] US; single institution	Home-visiting program (142), Usual care (140)	3	NYHA mean: 2.4 EF:43%	79	63	55	ACEI: 59 BB: 12	DM: 28 MI: 43	Med
Stewart et al., 1998[47] Australia; single institution	Home-visiting program (49), Usual care (48)	6	NYHA class III or IV: 48%	75	52	NR	ACEI: 81 BB: NR	DM: 22 IHD: 67 MI: 42 AF: 31	Med
Jaarsma et al., 1999[43] Netherlands; single institution	Home-visiting program (84), Usual care (95)	1, 3	NYHA III or IV: 100% LVEF: 34%	73	42	NR	ACEI or ARB: 70 BB: NR	DM: 30	Med
Stewart et al., 1999[46] Australia; single institution	Home-visiting program (100), Usual care (100)	6	NYHAIII or IV: 56% EF:37%	76	38	NR	ACEI or ARB: 71 BB: 28	DM: 34 IHD: 78 AF: 35	Med
Pugh et al., 2001[48] US; multicenter	Home-visiting program (27), Usual care (31)	6	NYHA III or IV: 51%	74	57	NR	NR	NR	High

Table 4. Characteristics of trials assessing home-visiting programs (continued)

Author, Year Setting	Intervention Category(N), Comparator (N)	Timing (ms)[a]	Baseline NYHA Class; Mean EF	Age (y)	Female (%)	Non-white (%)	Taking BB or ACEI at discharge (%)	Co-occurring Condition(s) (%)	Risk of Bias
Benatar et al., 2003[57] US; multicenter	Home-visiting program (108), Telemonitoring (108)	6	NYHA mean class: 3.1 EF: 38%	63	63	93	ACEI or ARB: 76 BB: 53	DM: 23 CAD or other cardiac disorders: 61	Unc.
Kimmelstiel et al., 2004[49] US; multicenter	Home-visiting program (97), Usual care (103)	3	NYHA II or III: 97%	72	42	NR	ACEI or ARB: 92 BB: 57	DM: 48	Med
Naylor et al., 2004[51] US; multicenter	Home-visiting program (118), Usual care (121)	3	EF<30%: 57%	76	57	36	NR	DM: 38 CAD: 49 Pulmonary disease: 30	Low
Sethares et al., 2004[44] US; single institution	Home-visiting program (33), Usual care (37)	3	NYHA mean class: 3 EF: 40%	76	53	8.5	ACEI or ARB: 61 BB: 49	NR	High
Thompson et al., 2005[56] UK; multicenter	Home-visiting program (58), Usual care (48)	6	NYHA III or IV: 40% EF: 30%	73	28	NR	ACEI or ARB: 69 BB: 18	DM: 21 MI: 52 AF: 30 chronic airways limitation: 24	High
Aldamiz-Echevarría Iraúrgui et al., 2007[52] Spain; single institution	Home-visiting program (137), Usual care (142)	6	EF:50%	76	61	NR	ACEI or ARB: 84 BB: 12	DM: 36 IHD: 30.5 AF: 49.6	Med
Holland et al., 2007[55] UK; multicenter	Home-visiting program (148), Usual care (143)	6	NYHA III or IV: 67%	77	36	NR	ACEI or ARB: 77 BB: 39	NR	Med
Kwok et al., 2007[50] Hong Kong; multicenter	Home-visiting program (44), Usual care (46)	6	EF <40%: 24%	78	55	100	ACEI or ARB: 57 BB: 22	DM: 33 IHD: 47 MI: 23 AF: 30 COPD: 10	Med

Table 4. Characteristics of trials assessing home-visiting programs (continued)

Author, Year Setting	Intervention Category(N), Comparator (N)	Timing (ms)[a]	Baseline NYHA Class; Mean EF	Age (y)	Female (%)	Non-white (%)	Taking BB or ACEI at discharge (%)	Co-occurring Condition(s) (%)	Risk of Bias
Triller et.al, 2008[45] US: multicenter	Home-visiting program (77), Usual care [a] (77)	6	NR	80	72	7	ACEI or ARB: 47 BB: 62	NR	Unc.

[a] Timing of readmission outcome.

[b] Triller et al. compared pharmacist home visits among a population of patients receiving home nursing visits.[45]

Abbreviations: ACEI = ACE inhibitor; AF = atrial fibrillation; ARB = angiotensin II receptor blocker; BB = beta-blocker; CAD = coronary artery disease; COPD = chronic obstructive pulmonary disease; DM = diabetes mellitus; EF = ejection fraction; HF = heart failure; IHD = ischemic heart disease; LVEF = left ventricular ejection fraction; Ms = months; Med = medium; MI = myocardial infarction; N = number (group size); NR = not reported; NYHA = New York Heart Association functional classification; QoL = quality of life; UK = United Kingdom; Unc. = unclear; US = United States; y = years.

Population

The mean age of participants was very similar across trials, ranging from 72 to 80 years. All studies enrolled both women and men; the percentage of women ranged from 28 to 72. The percentage of nonwhite participants ranged from 0 to 93 percent in the six trials that described patient race or ethnicity;[44,48,51,53,54,57] one trial did not comment on race but was conducted among Hong Kong residents.[50]

Seven trials reported the percentage of patients who had moderate or severe HF (New York Heart Association [NYHA] class III or IV); 40 percent to 67 percent of patients had moderate or severe HF.[43,46-49,55,56] Four studies reported the mean NYHA for patients: 2.8,[54] 3.0,[44,57] and 2.4.[53] One trial did not describe the severity of HF among patients.[45] Two trials commented on the percentage of patients with a reduced ejection fraction (EF): 57 percent of patients had an EF less than 35 percent in one trial,[51] and 24 percent of patients had an EF less than 40 percent in another.[50] One trial gave the mean EF for the population (50 percent) but no information on NYHA or the percentage of patients with a reduced EF.[52] Five trials did not describe the percentage of patients receiving a beta-blocker at discharge,[43,47,48,51,54] 12 percent to 62 percent of patients in other trails were prescribed a beta-blocker at discharge. Three studies did not report on the percentage of patients taking an angiotensin-converting-enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB) medication at discharge[48,51,54]; 47 percent to 92 percent of patients in other trials were on a ACEI or ARB at discharge.

In nine studies, 30 percent to 78 percent of patients had ischemic heart disease or coronary artery disease;[44,47-53,56,57] in all other trials, 20 percent to 48 percent of patients had diabetes.

Interventions

Most trials delivered a series of home visits immediately following discharge. Five trials involved one comprehensive home visit[43,46,47,49,56] following an index hospitalization; of these five studies, two specified that additional home visits would be provided if a person experienced more than two unplanned hospitalizations within 6 months.[46,47] In most trials, nurses conducted the home visits; one trial evaluated home visits led by pharmacists,[55] and one study evaluated whether additional home visits by a pharmacist among patients already receiving home-nursing visits was associated with improved outcomes.[45] In one study, a physician accompanied the nurse on the first home visit.[52] Most home visits began within 7 days of discharge; three studies

included visits within 24 to 48 hours of discharge,[51,53,54] and three studies specified that visits occurred within 14 days of discharge.[44,48,55]

All trials included education or training (or both) focused on self-management, diet, HF medications, and early recognition of symptoms; approximately half the trials delivered educational components both before discharge and during home visits. Two trials included planned, structured telephone calls in addition to home visits.[43,48] Most interventions offered a "patient hotline" for questions or advice throughout the intervention.

In one trial, usual care referred to usual "home health" that included nursing home visits in both groups.[45] Among other trials, descriptions of usual care tended to include "normal discharge planning," "followup as usual," or "care directed by inpatient team" with little other description provided.

Setting

One trial was conducted in Hong Kong,[50] two in the United Kingdom,[55,56] one in the Netherlands,[43] and two by the same group of investigators in Australia.[46,47] The remaining trials were conducted in the United States. Most trials were multicenter; seven were single center.[43,44,46,47,52-54]

Structured Telephone Support

Characteristics of Trials

We included 13 RCTs described in 15 publications comparing structured telephone support (STS) with usual care (Table 5).[58-68] One three-arm trial compared two modes of delivering STS (standard telephone versus videophone) with usual care.[65,66] Trial sample size ranged from 34 to 358. Only one trial reported a readmission rate at 30 days.[60]

We rated all but three trials as medium risk of bias. We rated three trials as high risk of bias primarily for high risk of selection bias and measurement bias.

Table 5. Characteristics of trials assessing structured telephone support

Author, Year, Setting	Intervention Category (N), Comparator (N)	Timing (m)[a]	Baseline NYHA Class; Mean EF	Age (y)	Female (%)	Non-white (%)	Taking BB or ACEI at discharge (%)	Co-occurring Con-dition(s) (%)	Risk of Bias
Rainville et al., 1999 [69] US; single institution	STS (17), Usual care (17)	6	NYHA III or IV: 85%	70	50	NR	ACEI or ARB: 88 BB: 44	NR	Med
Barth et al., 2001[58] US; single institution	STS (17), Usual care (17)	2	NR	75	53	NR	NR	DM: 33 Any other cardiac disease: 68	High

Table 5. Characteristics of trials assessing structured telephone support (continued)

Author, Year, Setting	Intervention Category (N), Comparator (N)	Timing (m)[a]	Baseline NYHA Class; Mean EF	Age (y)	Female (%)	Non-white (%)	Taking BB or ACEI at discharge (%)	Co-occurring Con-dition(s) (%)	Risk of Bias
Jerant et al., 2001[68] Jerant et al., 2003[67] US; single institution	STS (12) , Usual care (12), Tele-monitoring (13)	6	NYHA III or IV: 35%	70	54	51	ACEI or ARB: 68 BB: 38	IHD: 27	High
Riegel et al., 2002[59] US; multicenter	STS (130), Usual care (228)	3, 6	NYHA III or IV: 97% EF: 43%	72	51	NR	ACEI or ARB: 54 BB: 17	DM: 42 CAD: 65 AF: 24 COPD: 36	Med
Laramee et al., 2003[61] US; single institution	STS (141), Usual care (146)	2	NYHA III or IV: 35%	70	46	NR	ACEI or ARB: 82 BB: 63	DM: 43 Prior MI: 42 IHD: 71	Med
Tsuyuki et al., 2004[70] Canada; multicenter	STS (140), Usual care (136)	6	NYHA III or IV: 37%: EF: 31.5%	72	20	NR	ACEI or ARB: 85 BB: 43	NR	Med
Dunagan et al., 2005[64] US: single institution	STS (76), Usual care (75)	6	NYHA III or IV: 80% EF <40%: 58%	70	56	56	ACEI or ARB: 71 BB: NR	NR	Med
Cabezas et al., 2006[71] Spain; multicenter	STS (70), Usual care (64)	2, 6	NYHA III or IV: 10% EF: 51%	75	56	NR	ACEI or ARB: 72 BB: 7	DM: 34 MI: 20	Med
Riegel et al., 2006[60] US; multicenter	STS (69), Usual care (65)	1, 3, 6	NYHA III or IV: 81% EF <40%; 55%	72	54	100	ACEI or ARB: 75 BB: 54	DM: 59 IHD: 44 MI: 28 AF: 17	Med
Duffy et al., 2010[72] US; multicenter	STS (15), Usual care (17)[b]	6	NR	81	59	35 [b]	NR	NR	High

Table 5. Characteristics of trials assessing structured telephone support (continued)

Author, Year, Setting	Intervention Category (N), Comparator (N)	Timing (m)[a]	Baseline NYHA Class; Mean EF	Age (y)	Female (%)	Non-white (%)	Taking BB or ACEI at discharge (%)	Co-occurring Con-dition(s) (%)	Risk of Bias
Wakefield et al., 2008[65] Wakefield et al., 2009[66] US; single center (VAMC)	STS (47), Videophone (52), Usual care (49)	6	NYHA class III or IV: 72% EF: 41%	69	1	6	NR	NR	Med
Domingues et al., 2011[63] Brazil; single institution	STS (48), Usual care (63)	3	LVEF: 29%	63	32	19	NR	NR	Med
Angermann et al., 2012[62] Germany; multicenter	STS (352), Usual care (363)	6	NYHA III or IV: 40% EF: 30%	69	29	NR	ACEI or ARB: 88 BB: 80	DM: 36 CAD: 58 AF: 29 COPD: 19	Med

[a] Both groups in Duffy et al.[72] also received home healthcare co-intervention that included nursing home visits.

[b] Duffy et al.[72] reported in text that >35 percent of participants were minorities but did not provide exact numbers.

Abbreviations: ACEI = ACE inhibitor; AF = atrial fibrillation; ARB = angiotensin II receptor blocker; BB = beta-blockers; CAD = coronary artery disease; COPD = chronic obstructive pulmonary disease; DM = diabetes mellitus; EF = ejection fraction; HF = heart failure; IHD = ischemic heart disease; LVEF = left ventricular ejection fraction; m = months; MI = myocardial infarction; N = number (group size); NR = not reported; NYHA = New York Heart Association functional classification; STS = structured telephone support; US = United States; VAMC = Veterans Affairs Medical Center; Y = years

Population

The mean age of patients ranged from 63 to 81. One trial, conducted at a Veterans Affairs Medical Center (VAMC), enrolled primarily males (99 percent);[65] all other trials included 29 percent to 59 percent women. One trial was conducted in a completely Hispanic population.[60] Six trials did not report the race or ethnicity of participants;[58,61,62,69-71] all other trials enrolled 6 percent to 56 percent nonwhite participants.

Most trials included a majority of patients with moderate to severe HF; five trials included a minority of patients with moderate to severe HF.[61,62,68,70,71] Three studies did not report HF disease severity.[58,63,72] Four trials did not report the percentage of patients receiving HF pharmacotherapy (ACEI or ARB; beta-blocker) at discharge.[58,63,65,66,72] All other trials included 54 to 86 percent of patients who were prescribed an ACEI or ARB, and 7 to 63 percent of patients who were prescribed a beta-blocker. Most trials included patients with coexisting coronary artery disease or ischemic heart disease (20 percent to 79 percent); four studies did not describe the prevalence of coexisting heart disease among included patients.[58,68,69,72] Approximately half of the trials reported information on coexisting diabetes; the prevalence of coexisting diabetes ranged from 32 to 59 percent.[58-62,71]

Interventions and Comparators

All trials involved a series of scheduled, structured telephone calls to patients following discharge. Most trials averaged one or two calls during the intervention period. In most trials, the first telephone contact was within 7 days of discharge; in one, the first call occurred at 2 weeks after discharge;[70] and two trials did not describe the timing of the first call.[68,72] All studies included patient education. In most trials, education or self-care training began as an inpatient and was reinforced after discharge during telephone followup, but five trials did not include a predischarge educational component.[58-60,64,68,72] Most calls were delivered by nurses; two trials focused on STS delivered by a pharmacist.[69,71] Most trials included a patient-initiated hotline for questions or additional support.[58,61,62,64,65,69,71]

The types of other components delivered (in addition to STS) varied across trials. One intervention involved nurse case management at the time of discharge; care coordination with primary care and individualized discharge planning was part of the intervention (e.g., obtaining needed services for patients such as physical therapy, and facilitating communication in the hospital among the family and providers).[61] Two trials included an inpatient intervention that focused on optimizing evidence-based HF pharmacotherapy before discharge.[69,70] Six trials included coordination between intervention personnel and the patient's outpatient care providers during the course of telephone support.[58-62,65]

Usual care was described as planned outpatient followup in four trials.[61-63,65,66] One trial was conducted among patients receiving home health following discharge: "usual care" included in-home nursing visits administered by the home-health agency without additional details.[72]

Setting

Most trials were conducted in the United States—two in multicenter settings[59,60,72] and all others at a single center. One trial was conducted at a single center in Brazil,[63] and three trials were conducted in multicenter settings in Europe and Canada.[62,70,71]

Telemonitoring

Characteristics of Trials

We included eight RCTs described in nine publications (Table 6). Seven RCTs compared remote monitoring of clinical data (e.g., weight, vital signs) with usual care,[67,68,73-78] and one compared remote monitoring of clinical data with home nurse visits.[57] Sample sizes ranged from 37 to 280 patients. Only one trial reported a readmission rate at 30 days.[78]

We rated four trials as medium risk of bias. We rated two trials as high risk of bias and two others as unclear risk of bias; the primary problems were inadequate handling of missing data and unclear fidelity to the protocol.

Table 6. Characteristics of trials assessing telemonitoring

Author, Year, Setting	Intervention Category(N), Comparator (N)	Timing (m)[a]	Baseline NYHA Class; Mean EF	Age (y)	% Female	Non-white (%)	Taking BB or ACEI at discharge (%)	Co-occurring Condition(s) (%)	Risk of Bias
Jerant et al., 2001[68] Jerant et al., 2003[67] US; single institution	Telemonitoring (13), Usual care (12), STS (12)	6	NYHA III or IV: 35%	70	54	51	ACEI or ARB: 68 BB: 38	IHD: 27	High
Benatar et al., 2003[57] US; multicenter	Telemonitoring (108), Home-visiting program (108)	6	NYHA mean class: 3.1 EF: 38%	63	63	93	ACEI or ARB: 76 BB: 53	DM: 23 CAD or other cardiac disorders: 61	Unc
Goldberg et al., 2003[75] US; multicenter	Telemonitoring (138), Usual care (142)	6	NYHA III-IV: 100%	59	32	36	ACEI: 74 ARB: 16 BB: 38	DM: 41 MI: 39 AF: 35	Med
Schwarz et al., 2008[74] US; single institution	Telemonitoring (51), Usual care (51)	3	NYHA class III or IV: 79%	78	52	19	NR	DM: 50 MI: 51 AF: 30 COPD: 29	Med
Woodend et al., 2008[77] Canada; single institution	Telemonitoring (62), Usual care (59)	3	NYHA III or IV: 62%	67	28	NR	NR	Prior MI: 57	High
Dar et al., 2009[76] UK; multicenter	Telemonitoring (91), Usual care (91)	6	EF ≥40%: 39%[b]	72	34	20 (South Asian)	ACEI or ARB: 88 BB: 56	DM: 36 CAD: 55 Prior MI: 48 COPD: 91	Med
Dendale et al., 2012[73] Belgium; multicenter	Telemonitoring (80), Usual care (80)	6	NYHA mean class: 3.0 LVEF: 35%	76	35	NR	NR	NR	Unc
Pekmezaris et al., 2012[78] US; multicenter	Telemonitoring (83), Usual care (85)[c]	1, 3	NR	82	62	9	NR	NR	Med

[a] Timing of readmission outcome.

[b] EF data reported in Dar et al. are based on data from 168 patients (92 percent of total sample).[76]

[c] In Pekmezaris et al., both groups received home health care, including nursing home visits.[78]

Abbreviations: ACEI = ACE inhibitor; AF = atrial fibrillation; ARB = angiotensin II receptor blocker; BB = beta-blocker; CAD = coronary artery disease; COPD = chronic obstructive pulmonary disease; DM = diabetes mellitus; EF = ejection fraction; HF = heart failure; IHD = ischemic heart disease; LVEF = left ventricular ejection fraction; m = months; Med. = medium; MI = myocardial infarction; N = group size; NR = not reported; NYHA = New York Heart Association functional classification; UK = United Kingdom; Unc = unclear; US = United States; Y = years

Population

The mean age of patients ranged from 59 to 82 years. Half of the trials enrolled fewer women than men (range, 28 percent to 35 percent women);[73,75-77] the remainder included 52 percent to 63 percent women.[57,67,68,74,78] One trial was conducted primarily in nonwhite patients (86 percent African American, 6 percent Hispanic, 1 percent Asian);[57] the other studies included 9 percent to 51 percent nonwhite patients[67,68,74-76,78] or did not report information on race.[73,77]

Most trials enrolled a majority patients with moderate to severe HF based on NYHA classification. In one trial, a majority of patients had less severe HF (65 percent with NYHA class II HF);[67,68] two trials did not report baseline disease severity based on NYHA classification.[76,78]

Four trials described the percentage of patients on an ACEI or ARB at discharge (68 percent to 88 percent of patients) and the percentage of patients on a beta-blocker at discharge (38 percent to 56 percent of patients).[57,68,75,76] Three trials did not report information on pharmacotherapy at discharge,[73,77,78] and one trial reported the mean number of "heart medications" at discharge (5.5 medications) without defining which medications were counted.[74]

The proportion of patients with coronary artery disease or prior myocardial infarction(s) ranged from 27 percent to 61 percent in most trials.[57,67,68,74-77] The proportion of patients with diabetes ranged from 23 percent to 50 percent in four RCTs.[57,74-76]

Interventions and Comparators: Remote Monitoring of Clinical Data

We included five RCTs of remote clinical data monitoring using equipment installed in a patient's home that transmitted clinical data to a central site.[57,73-76] Remote monitoring equipment was generally either sent home with a patient from the hospital or delivered within 1 to 3 weeks of discharge. In three RCTs, patients also answered questions about symptoms (e.g., shortness of breath, edema) through the remote monitoring system.[74-76] In four RCTs, nurses contacted patients or physicians (or both) when weights or vital signs were outside protocol-defined parameters.[57,74-76] In one RCT, alerts about abnormal clinical data were sent directly to the primary care clinician and HF clinic.[73]

Remote monitoring of clinical data was compared with usual care in four RCTs.[73-76] Usual care was defined as standard care from primary care clinicians or cardiologists (or both) in three trials;[73-75] in one trial, usual care included an initial home visit to deliver education about HF self-monitoring, telephone support, and care from a specialized HF clinician.[76] One trial randomized patients to either home nursing visits or nurse remote monitoring.[57]

Interventions and Comparators: Remote Monitoring with Video Clinical Visits

Three trials used specialized equipment to allow for video assessments and interactions with patients.[67,68,77,78] The equipment could also check clinical data such as blood pressure or included stethoscopes to allow remote heart and lung auscultation. The specialized equipment was generally delivered to patient's homes within 48 hours to 7 days of discharge from the hospital.

In one trial, the intervention group was instructed to monitor weight and blood pressure daily; this information was then transmitted to a central site and monitored by a nurse who also completed video conferences with the patients; this group was compared with usual care.[77] One RCT had three arms and compared (1) video nursing visits including video interaction and a remote stethoscope with (2) telephone nursing visits and with (3) usual care; both intervention groups also had access to a nurse hotline for questions or concerns.[67,68] In both studies, usual care

was defined as directed by a primary care physician or cardiologist. In one usual-care group, patients also had a telephone number to access an advanced practice nurse with questions about their care;[77] patients in the other usual-care group received two nurse home visits (after discharge and at 60 days), during which standard education and clinical assessment were conducted.[67,68]

One trial evaluated adding video nursing visits to home nursing visits through a home health care agency; the comparison was usual home nursing visits without additional video visits.[78] The equipment in this trial allowed for blood pressure checks and stethoscope examination during the video visits.[78] In both groups, the frequency of home visits was determined by a nurse's judgment; in addition, all nurses followed standardized disease management guidelines to manage patients.

All trials included an educational component; most delivered education after discharge. One trial delivered predischarge education about general self-management, weight monitoring, and low-sodium diets.[75] In five trials, nurses delivered general HF self-care education after discharge by telephone, video, or in person.[67,68,73,76 ,77,78] Educational content included weight monitoring in four trials,[67,68,73-75] low-sodium diets in five trials,[57,67,68,73,75,78] medication education and adherence promotion in four trials,[57,67,68,73,78] and exercise promotion in one trial.[73]

Setting

Five trials were conducted in the United States; two were at a single center,[67,68,74] and the remainder were multicenter.[57,75,78] Three trials were conducted outside the United States: one in a multicenter setting in Belgium,[73] one at a single institution in Canada,[77] and one in a multicenter setting in the United Kingdom.[76]

Clinic-based Interventions

Characteristics of Trials

We included seven RCTs described in nine publications (Table 7). Six compared HF specialty clinic interventions with usual care[79-86] and one compared enhanced access (increased access) to primary care with usual care.[87] Sample sizes ranged from 98 to 443. One trial reported a readmission rate at 30 days.[80]

Of these seven trials, we rated six as low or medium risk of bias; we rated one trial as unclear, primarily because the validity of health care utilization measures was not well described.

Table 7. Characteristics of trials assessing clinic-based interventions

Author, Year, Setting	Intervention Category(N), Comparator (N)	Timing (m)[a]	Baseline NYHA Class; Mean EF	Age (y)	Female (%)	Nonwhite (%)	Taking BB or ACEI at discharge (%)	Co-occurring Condition(s) (%)	Risk of Bias
McDonald et al., 2001[80] McDonald et al., 2002[81] Ledwidge et al., 2003[82] Ireland; single institution	At 3 months [b]: Clinic-based (MDS-HF) (51), Usual care (47) At 30 days: Clinic-based (MDS-HF) (35), Usual care (35)	1, 3[b]	EF<45%: 63%[b]	71[b]	34[b]	NR	ACEI or ARB: 61[b] BB: NR	NR	Unc
Kasper et al., 2002[83] US; multicenter	Clinic-based (MDS-HF) (102), Usual care (98)	6	NYHA III: 59% (no patients with class IV) EF <45%: 88%	64	40	35	ACEI or ARB: 86 BB: 39	DM: 40	Low
Ducharme et al., 2005[85] Canada; single institution	Clinic-based (MDS-HF) (115), Usual care (115)	6	NYHA III or IV: 91% EF: 35%	69	28	NR	ACEI or ARB: 80 BB: 43	DM: 30 CAD: 66 Prior MI: 50	Low
Liu et al., 2012[86] Taiwan; single institution	Clinic-based (MDS-HF) (53), Usual care (53)	6	NYHA III or IV: 62% EF: 28%	61	35	100	ACEI or ARB: 40 BB: 65	DM: 46	Low
Stromberg et al., 2003[84] Sweden; multicenter	Clinic-based (Nurse-led) (52), Usual care (54)	3	NYHA III or IV: 82%	78	39	NR	ACEI or ARB: 82 BB: 58	DM: 24 IHD: 68	Low
Ekman et al., 1998[79] Sweden; single institution	Clinic-based (Nurse-led) (79), Usual care (79)	6	NYHA mean class: 3.2 EF: 41% [c]	80	42	NR	ACEI or ARB: 37 BB: 30	DM: 28 AF: 41 Prior MI: 45	Med

Table 7. Characteristics of trials assessing clinic-based interventions (continued)

Author, Year, Setting	Intervention Category(N), Comparator (N)	Timing (m)[a]	Baseline NYHA Class; Mean EF	Age (y)	Female (%)	Nonwhite (%)	Taking BB or ACEI at discharge (%)	Co-occurring Condition(s) (%)	Risk of Bias
Oddone et al., 1999[87] US; multicenter	Clinic-based (Primary Care) (222), Usual care (221)	6	NYHA III or IV: 53%	65	1	34	ACEI or ARB: 74 BB: 12	NR	Med

[a] Timing of readmission outcome.

[b] Data comes from the McDonald, 2002[81] publication; percentages vary slightly from companion studies.[80,82]

[c] EF values reported in Ekman et al are based on data from 99 patients (63 percent of total sample).[79]

Abbreviations: ACEI = ACE inhibitor; AF = atrial fibrillation; ARB = angiotensin II receptor blocker; BB = beta-blocker; CAD = coronary artery disease; DM = diabetes mellitus; EF = ejection fraction; HF = heart failure; IHD = ischemic heart disease; m = months; MDS-HF = multidisciplinary heart failure clinic; Med. = medium; MI = myocardial infarction; N = group size; NR = not reported; NYHA = New York Heart Association functional classification; Unc. = unclear; US = United States; Y = years

Population

The mean age of patients ranged from 61 to 80 years. The percentage of female patients ranged from 39 percent to 42 percent in most trials; one trial focused on increased primary care access for HF patients was conducted in a VAMC setting (1 percent were women). Four trials did not include information on race or ethnicity. One trial was conducted only among Taiwanese patients;[86] the percentage of nonwhite subjects in two U.S. trials was approximately 34 percent.[83,87] Most trials enrolled a majority of subjects with moderate to severe HF based on NYHA classification. The percentage of patients on pharmacotherapy at discharge ranged from 37 percent to 86 percent for an ACEI or ARB and 30 percent to 65 percent for beta-blockers. Most studies included populations with a variety of coexisting chronic conditions: 24 percent to 46 percent of patients had diabetes, and 46 percent to 71 percent of patients had a prior history of myocardial infarction (MI). One trial reported no information on coexisting diabetes, cardiac disease, or respiratory disorders.[87]

Interventions and Comparators

All trials involved a series of prescheduled outpatient clinic visits following discharge, regular structured telephone calls to patients beginning within 7 days after the hospital discharge or enrollment, and individualized care planning. Among the six studies evaluating HF clinic interventions, two were described as "nurse-led" and focused more on patient education delivered by nurses during scheduled clinic appointments than on multidisciplinary (MDS)-HF management.[79,84] The others were described as MDS-HF clinic interventions and involved more emphasis on physician contact and access to a multidisciplinary care team (cardiology, nurses, dieticians, pharmacists) than nurse-led clinics. In general, most trials also included an educational component. Two trials included education on self-care delivered before discharge and education reinforcement during telephone followup.[81,87] One trial focused on enhanced access to primary care.[87] Three services coordinated care with a patient's primary care physician by scheduling appointments for acute needs or alerting physicians to changes in symptoms.[79,81,86]

All trials provided a brief description of usual care that included "management in accordance with current clinical practice" or stated that patients received conventional followup in primary health care.

Setting

Three trials were conducted in North America,[83,85,87] three in Europe,[79-82,84] and one in Asia.[86]

Primarily Educational Interventions

Characteristics of Trials

We included four RCTs that compared primarily educational interventions with usual care (Table 8).[88-91] Sample size ranged from 110 to 302. No trials reported a 30-day readmission rate. We rated one trial as low risk of bias and one as medium risk of bias. We rated one trial as high risk of bias and one as unclear risk of bias, primarily because of potential for measurement bias and inadequate handling of missing data, respectively.

Table 8. Characteristics of trials assessing primarily educational interventions

Author, Year, Setting	Intervention Category(N), Comparator (N)	Timing (m)[a]	Baseline NYHA Class; Mean EF	Age (y)	Female (%)	Nonwhite (%)	Taking BB or ACEI at discharge (%)	Co-occurring Con-dition(s) (%)	Risk of Bias
Koelling et al., 2005[91] US; single institution	Primarily Educational (107), Usual Care (116)	6	EF: 27%	65	42	22	ACEI or alternative: 61 BB: 55	CAD: 64	Low
Linne et al., 2006[90] Sweden; multicenter	Primarily Educational (122), Usual Care (108)	6	EF < 40%: 100%	70	29	NR	ACEI or ARB: 80 BB: 49	NR	Unc.
Nucifora et al., 2006[89] Italy; single institution	Primarily Educational (99), Usual Care (101)	6	NYHA III or IV: 65%	73	38	NR	ACEI or ARB: 80 BB: 13	DM: 26 IHD: 46 COPD: 27	Med.
Albert et al., 2007[88] US; single institution	Primarily Educational (37), Usual Care (39)	3	EF <40%: 100%	60	23	17	ACEI or ARB: 88 BB: 56	DM: 33 CAD: 66 MI: 45 AF: 37	High

[a] Timing of readmission outcome.

Abbreviations: ACEI = ACE inhibitor; AF = atrial fibrillation; ARB = angiotensin II receptor blocker; BB = beta-blocker; CAD = coronary artery disease; COPD = chronic obstructive pulmonary disease; DM = diabetes mellitus; EF = ejection fraction; HF = heart failure; IHD = ischemic heart disease; LVEF = left ventricular ejection fraction; m = months; Med. = medium; MI = myocardial infarction; N = group size; NR = not reported; NYHA = New York Heart Association functional classification; Unc = unclear; US = United States; VAMC = Veterans Affairs Medical Center; Y = years

Population

Mean age ranged from 60 to 73 years. Studies included 23 percent to 42 percent women. Two trials described the race or ethnicity of patients (17 percent to 22 percent nonwhite).[88,91]

Three trials included patients with an EF of <40 percent,[88,90,91] and one trial included a majority of patients with moderate to severe HF.[89] The majority of patients were on an ACEI or ARB at discharge (60 percent to 88 percent). Approximately half of patients in three studies were on a beta-blocker at discharge.[88,90,91]

One study did not describe the prevalence of coexisting conditions among patients.[90] Two trials reported prevalence rates of 26 percent and 33 percent of diabetes.[88,89] Three studies included populations among whom 46 percent to 66 percent of patients had coronary artery disease.[88,89,91]

Interventions and Comparator

All studies involved primarily educational interventions aimed at preventing HF readmission; however, they differed in the mode of delivery and timing of education in relationship to the index HF hospitalization. One study compared the effects of a 1-hour in-person patient education program with usual discharge care; no other components were delivered after discharge.[91] Two trials investigated the effects of HF education delivered via technology.[88,90] One study included predischarge HF education focused on HF symptoms and treatment that was delivered via CD; the same educational CD was repeated 2 weeks after discharge (patients returned to the hospital to view the CD).[90] Another study evaluated the effects of a 60-minute, six-chapter video on HF that was intended to be viewed at home.[88] One study featured predischarge intensive education about HF symptoms and treatment administered by a nurse; in addition, one telephone call was conducted 3 to 5 days after discharge with the goal of reinforcing education, a nurse hotline was available for questions, and education was reinforced at scheduled outpatient visits (15 days, 1 and 6 months).[89]

Setting

Two single-center studies were conducted in the United States,[88,91] and one in Italy.[89] One multicenter study was conducted in Sweden.[90]

Other Interventions

Characteristics of Trials

We included two RCTs evaluating unique interventions that did not fit into any other category (Table 9). One used peer support for patients with HF following discharge,[92] and the other examined the effect of cognitive training on patients with HF and coexisting cognitive dysfunction.[93] Sample size ranged from 88 to 125. Both trials reported a 30-day readmission rate. We rated one trial as medium risk of bias and the other as high risk of bias, primarily because of a high risk of selection bias and inadequate handling of missing data.

Table 9. Characteristics of trials assessing other interventions

Author, Year, Setting	Intervention Category(N), Comparator (N)	Timing (m)[a]	Baseline NYHA Class; Mean EF	Age (y)	Female (%)	Nonwhite (%)	Taking BB or ACEI at discharge (%)	Co-occurring Condition(s) (%)	Risk of Bias
Riegel et al., 2004[92] US; multi-center	Peer support (45), Usual care (43)	1, 3	NYHA III or IV: 64% EF: 45%	73	58	NR	NR	DM: 46 History of MI: 35 COPD: 25	High
Davis et al., 2012[93] US; single institution	Self-care teaching and cognitive training (63), Usual care (62)	1	NYHA III or IV: 53% EF: 34%	59	53	69	NR	DM: 39 AF: 26 COPD: 22 MCI: 100	Med.

[a] Timing of readmission outcome.

Abbreviations: ACEI = ACE inhibitor; AF = atrial fibrillation; ARB = angiotensin II receptor blocker; BB = beta-blocker; COPD = chronic obstructive pulmonary disease; DM = diabetes mellitus; EF = ejection fraction; HF = heart failure; m = months; MCI = mild cognitive impairment; Med. = medium; MI = myocardial infarction; N = group size; NR = not reported; NYHA = New York Heart Association functional classification; US = United States; Y = years

Population

Mean age was 59 and 73 years. Approximately half the patients in both studies were women. Only the trial assessing cognitive training described patient race or ethnicity (69 percent nonwhite).[93] Both trials enrolled a majority of patients with moderate to severe HF. Neither study reported on the percentage of patients taking an ACEI or beta-blocker at discharge. Patients with coexisting diabetes made up 39 percent or 46 percent of the study populations. The trial assessing cognitive training screened patients for inclusion with the Montreal Cognitive Assessment;[94] patients were included if they had a score suggesting mild cognitive impairment (score between 17 and 25 out of 30; scores less than 17 suggest dementia).

Interventions and Comparators

One study focused on dealing with impairments in memory and executive function through environmental manipulations and training strategies and on improving self-confidence related to the ability to provide self-care.[93] Specifically, during the hospitalization, each patient was provided a spiral workbook with pictograms and space to personalize a self-care schedule focused on their medication schedule and future appointments. Patients were provided with typical HF self-care problems and a case-manager helped the patient solve problems; an audiotape of the sessions was provided to the patient at discharge. One telephone call was conducted after discharge (24 to 72 hours) for a teach-back session.[93] Usual care was described as "standard discharge teaching for HF, including verbal review of a HF patient education booklet."

The other trial focused on peer monitoring as a means of social support and mentoring on self-care for patients with HF.[92] The investigators recruited nine patients with HF and trained them as mentors; mentors were described as elderly men and women with mild to moderate HF. Patients randomized to peer support chose the gender and geographic location of their mentor.

Contact began during the index hospitalization (in person) or immediately after discharge via telephone contact. Mentoring occurred during home visits, telephone calls, and joint outings; weekly contact was encouraged for the 30 days following discharge and then at least monthly for 3 months. Usual care was described as inpatient education on HF.

Setting

Both studies occurred in the United States. The study assessing peer support was conducted in a multicenter setting,[92] and the trial assessing cognitive training was conducted at a single center.[93]

KQ 1. Transitional Care Interventions and Health Care Utilization Outcomes

Key Points: All-cause Readmissions

- Home-visiting programs that are of higher intensity (e.g., first visit within 24 hours and multiple planned home visits) were efficacious in reducing all-cause readmissions at 30 days (low SOE). Lower intensity home-visiting programs were not efficacious in reducing 30-day all-cause readmissions (low SOE).
- Home-visiting programs were efficacious in reducing all-cause readmissions at 3 and 6 months (moderate SOE).
- MDS-HF clinic interventions were efficacious in reducing all-cause readmissions at 6 months (moderate SOE).
- Structured telephone support (STS) was not efficacious in reducing all-cause readmissions at 2 to 3 months (moderate SOE) or 6 months (low SOE).
- Telemonitoring did not reduce all-cause readmissions at 2 to 3 months or 6 months (moderate SOE).
- Evidence was insufficient to determine whether any intervention is efficacious in reducing all-cause readmissions at 30 days, or to support the efficacy of the following intervention categories at any timepoint: nurse-led HF clinic interventions, primary care clinic interventions, cognitive training, and primarily educational interventions.

Key Points: Heart Failure Readmissions

- Home-visiting programs and STS interventions were efficacious in reducing HF readmissions at 3 months (moderate SOE for both interventions).
- STS interventions were efficacious in reducing HF readmissions at 6 months (moderate SOE).
- Telemonitoring interventions were not efficacious in reducing HF readmissions at 6 months (moderate SOE).
- Evidence was insufficient to determine whether any intervention is efficacious in reducing HF readmissions at 30 days, or to support the efficacy of the following intervention categories at any timepoint: nurse-led HF clinic interventions, MDS-HF clinic interventions and primarily educational clinic interventions.

Key Points: Combined All-Cause Readmission or Death

- Despite having only a single trial of home visiting that reported rates at 30 days, this intervention category also consistently reduced readmission rates over 3 and 6 months; therefore, we considered home-visiting programs efficacious in reducing the combined outcome of all-cause readmission or death at 30 days (low SOE).
- Home-visiting programs were efficacious in reducing the combined endpoint of all-cause readmission or death) at 6 months (moderate SOE).
- STS and primarily educational interventions were not efficacious in reducing all-cause readmissions or death at 6 months (low SOE).
- Evidence was insufficient to determine whether the following intervention categories were efficacious in reducing all-cause readmissions or death: STS at 3 months, nurse-led clinic interventions.

Key Points: Emergency Room Visits, Acute Care Visits, Hospital Days

- Few trials reported rates of emergency room (ER) or acute care visits.
- STS interventions did not increase or decrease emergency room visits at 6 months (low SOE).
- Evidence was insufficient to determine whether other intervention categories increased or decreased ER or acute care visits at any timepoint.
- STS reduced the number of hospital days of subsequent readmissions at 3 and 6 months; evidence was insufficient to determine whether other intervention categories increase or decrease future hospital days.

Key Points: Comparative Effectiveness

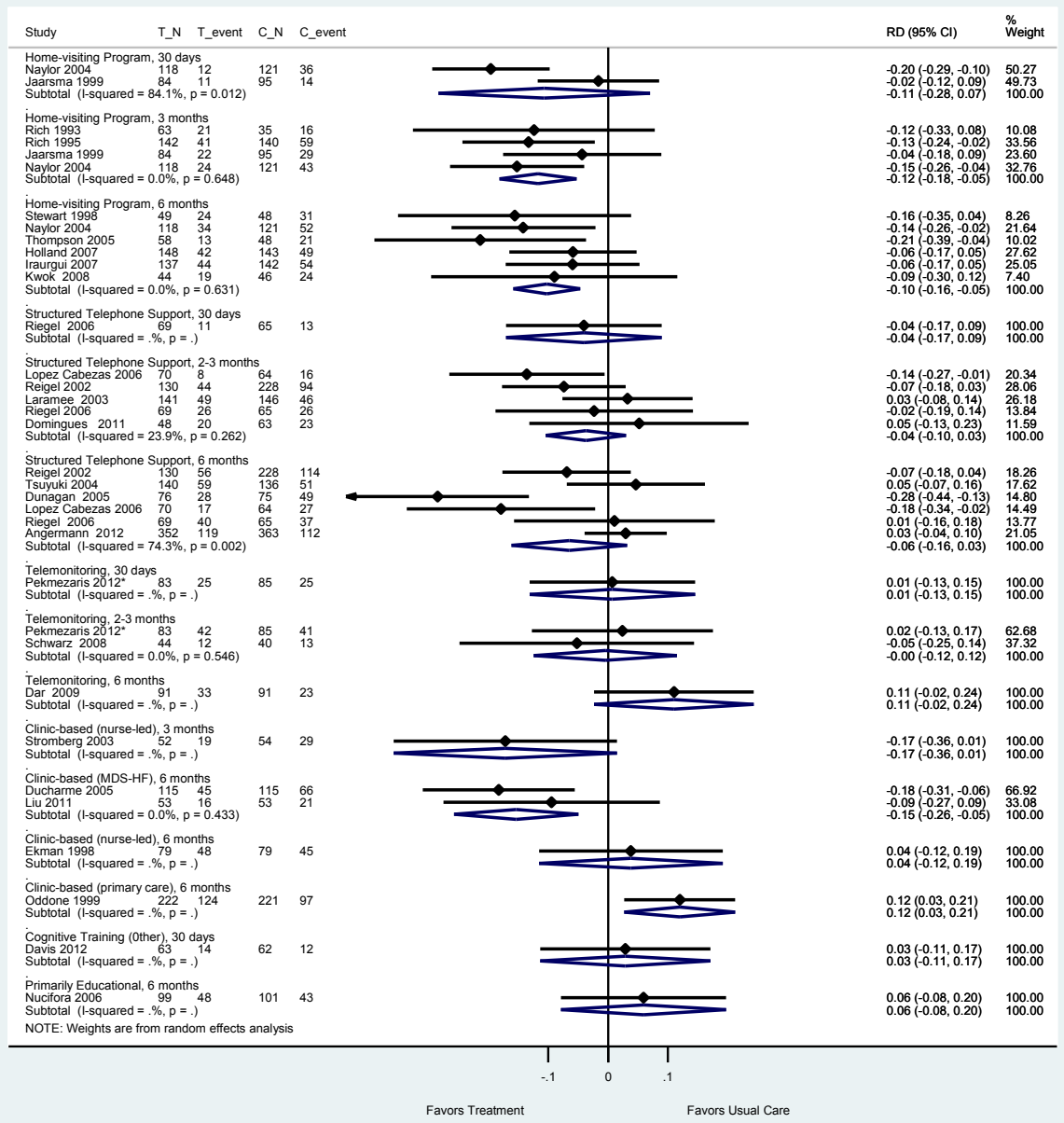
- Direct evidence was insufficient to determine whether one type of transitional care intervention is more or less efficacious than any other type of intervention for any health care utilization outcome.

Detailed Synthesis

All-Cause Readmissions: Transitional Care Interventions Compared with Usual Care

Figure 3 presents our meta-analysis of trials reporting all-cause readmissions (number of people readmitted) stratified by intervention category and outcome timing. No interventions reduced 30-day all-cause readmissions. Home-visiting programs reduced all-cause readmissions at 3 and 6 months; MDS-HF clinic-based interventions reduced all-cause readmissions at 6 months. We present detailed results by intervention category and outcome timing below.

Figure 3. All-cause readmissions for transitional care interventions compared with usual care, by intervention category and outcome timing



Home-Visiting Programs

At 30 days, our meta-analysis (two trials) found no difference in all-cause readmissions between the patients receiving home visits and those receiving usual care (RD, -0.11; 95% CI, -0.28 to 0.07).[43,51] However, there was considerable statistical heterogeneity between these two trials (I^2 =84.1%) and also important differences in the intervention delivered. Although both trials included comprehensive inpatient education and individualized discharge planning, the interventions differed in the timing of the first home visit and total number of planned home visits.

Briefly, in the trial by Naylor et al., an advanced practice nurse visited patients at home within 24 hours of discharge, and a total of eight home visits were planned. In the trial by Jaarsma et al., a phone call was made to the patient within 7 days following discharge to

schedule a home visit; most visits were scheduled within 10 days of discharge and no additional visits were planned. The trial by Naylor et al., which evaluated a more intensive intervention, found that 20 percent fewer patients receiving home visits were readmitted within 30 days than patients receiving usual care (RD, -0.20; 95% CI, -0.29 to -10).[51] The trial by Jaarsma et al. found a trend towards reduction in all-cause readmissions in patients receiving the intervention versus controls that was not statistically significant (RD, -0.02; 95% CI -0.12 to 0.09).[43]

At 3 months, our meta-analysis (four trials) found that 12.0 percent fewer patients receiving home visits were readmitted than patients receiving usual care (RD, -0.12; 95% CI, -0.18 to -0.05).[43,51,53,54] At 6 months after discharge (six trials), 10.0 percent fewer patients receiving home visits were readmitted than patients receiving usual care (RD, -0.10; 95% CI, -0.16 to -0.05).[47,50-52,55,56]

Two trials reported the number of total readmissions per group (rather than people readmitted) at 6 months. In one trial (N=200), patients receiving home visits had fewer unplanned readmissions (68) than those receiving usual care (118) ($p = 0.031$).[46] In another trial (N=200), all-cause readmissions did not differ between patients receiving home visits and those receiving usual care (measured as mean readmissions per patient-year alive: RR, 0.89; $p=0.61$).[49]

Structured Telephone Support

One trial (N= 134) reported all-cause readmissions at 30 days; the readmission rate did not differ between patients receiving STS and those receiving usual care (RD, -0.041; 95% CI, -0.171 to 0.089).[60]

At 2 to 3 months, our meta-analysis (five trials) found no difference in the readmission rate between patients receiving home visits and those receiving usual care (RD, -0.04; 95% CI, -0.10 to 0.03).[59,61,63,71] Similarly, at 6 months our meta-analysis (six trials) found no difference in the readmission rate between those two groups (RD, -0.06; 95% CI, -0.16 to 0.3).[59-62,70,71]

Telemonitoring

One trial (N=168) reported all-cause readmissions at 30 days; the readmission rate among patients receiving telemonitoring and those receiving usual care did not differ (RD, -0.01; 95% CI, -0.13 to 0.15).[78]

At 3 months, our meta-analysis (two trials) found no difference in the readmission rate between patients receiving telemonitoring and those receiving usual care (RD, -0.00; 95% CI, -0.12 to 0.012).[74,78]At 6 months, one trial (N=182) found no difference in the readmission rate between these groups (RD, 0.11; 95% CI, -0.02 to 0.24).[76]

Four telemonitoring studies reported the total number of readmissions per group (rather than the number of people readmitted); all-cause readmissions did not differ between patients receiving telemonitoring and those receiving usual care at 30 days,[67] 3 months,[77] or 6 months.[67,73,75]

Clinic-Based Interventions

Given heterogeneity in the interventions among the clinic-based interventions, we pooled data separately by clinic setting: MDS-HF clinic, nurse-led HF clinic, and primary care clinic. Among the MDS-HF interventions, our meta-analysis (two trials) found that patients receiving the intervention had 15 percent fewer readmissions than patients receiving usual care (RD, -0.15; 95% CI, -0.26 to -0.05).

One trial (N=106) assessing a nurse-led intervention found no difference in all-cause readmissions between patients receiving the intervention and those receiving usual care at 3 months (RD, -0.17; 95% CI, -0.36 to 0.01).[84] Similarly, another trial (N=158) assessing a nurse-led HF clinic intervention found no difference in all-cause readmissions between the intervention and control group at 6 months (RD, 0.04; 95% CI, -0.12 to 0.19).[79]

One trial (N=443) found that patients with HF who had increased (or enhanced) access to primary care (through a Department of Veterans Affairs [VA] health care setting) following discharge had 12 percent more all-cause readmissions than patients receiving usual care (RD, 0.12 percent; 95% CI, 0.03 to 0.21).[87]

Primarily Educational Interventions

One trial found no difference in all-cause readmissions at 6 months between patients receiving intensive predischarge education and controls (RD, 6 percent; 95% CI, 0.08 to 0.20).[89]

Other Interventions

A trial (N=125) of cognitive training among patients with HF and coexisting cognitive dysfunction found no difference in 30-day readmissions between patients receiving the intervention and controls.[93]

Heart Failure Readmissions: Transitional Care Interventions Compared with Usual Care

A meta-analysis of trials reporting HF readmissions (number of people readmitted) is shown in Figure 4. Overall, fewer trials reported HF specific readmissions rates. STS reduced HF readmissions at 6 months. We present detailed results by intervention category and outcome timing below.

Home-Visiting Program

At 3 months, one trial (N=282) found that patients receiving home visits had 14.0 percent fewer readmissions than patients receiving usual care (RD, -0.14; 95% CI, -0.23 to -0.04).[53] One other trial (N=200) reported the total number of readmissions per group rather than the number of patients readmitted; patients receiving home visits had fewer total HF readmissions than did patients receiving usual care (measured as readmissions per patient year alive, RR, 0.54; $p<0.001$).[49]

Structured Telephone Support

One trial (N=134) found no difference in HF readmissions between patients receiving STS and those receiving usual care at 30 days (RD, -0.05; 95% CI, -0.16 to 0.06).[60]

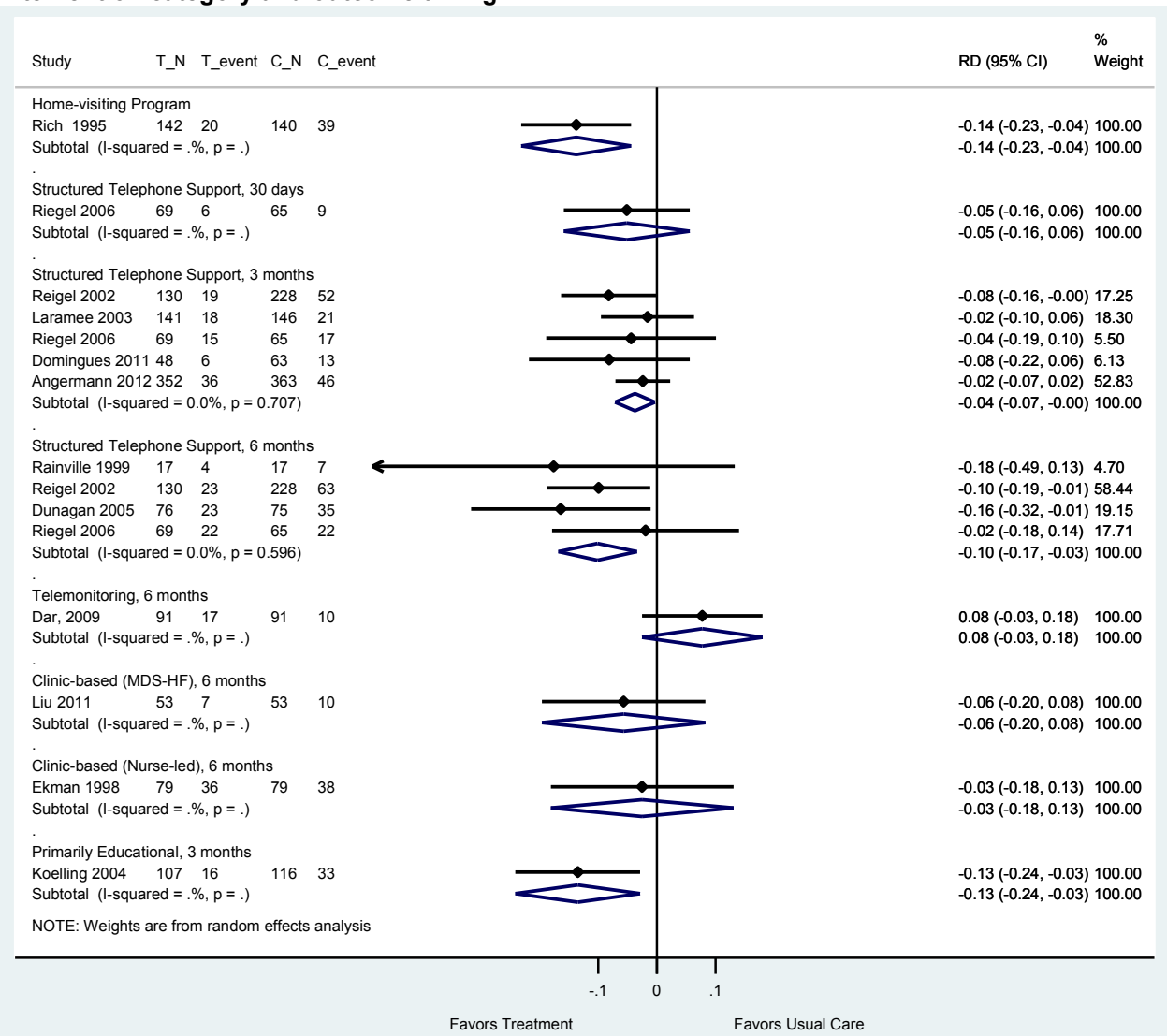
At 3 months, our meta-analysis (five trials) found that people receiving STS had 4 percent fewer HF readmissions than controls (RD, -0.04; 95% CI, -0.07 to -0.004).[59-63] At 6 months (four trials), 10 percent fewer patients receiving STS were readmitted because of HF than patients receiving usual care (RD, -0.10; 95% CI, -0.17 to -0.03).

Telemonitoring

At 6 months, one trial (N=182) found no difference in the number of patients readmitted for HF between patients receiving telemonitoring and those receiving usual care (RD, 0.08; 95% CI,

-0.03 to 0.18).[76] Two trials reported the total number of readmissions per group (rather than patients readmitted); neither study found a difference between these two groups.[73,75]

Figure 4. HF readmissions for transitional care interventions compared with usual care, by intervention category and outcome timing



Clinic-Based Interventions

Two clinic-based interventions reported HF readmissions at 6 months, one MDS-HF clinic intervention and one nurse-led clinic intervention. The MDS-HF trial (N=106) found no difference in the number of patients readmitted for HF between patients receiving the intervention and those receiving usual care (RD, -0.06; 95%CI, -0.20 to 0.08).[86] The nurse-led trial (N=158) also found no difference in the number of people readmitted for HF between the intervention and control groups (RD, -0.03; 95% CI, -0.20 to 0.08).[79]

Primarily Educational Interventions

One trial (N=123) found that 13 percent fewer patients receiving face-to-face intensive HF education before discharge were readmitted for HF than patients receiving usual care at 3 months

(RD, -0.13; 95% CI, -0.24 to -0.03).[91] A sensitivity analysis that also included a second educational intervention trial rated as high risk-of-bias found no difference in HF-specific readmission rates between patients receiving an educational intervention and those receiving usual care (RD, -0.07; 95% CI, -0.24 to 0.10; Appendix F).[88,91]

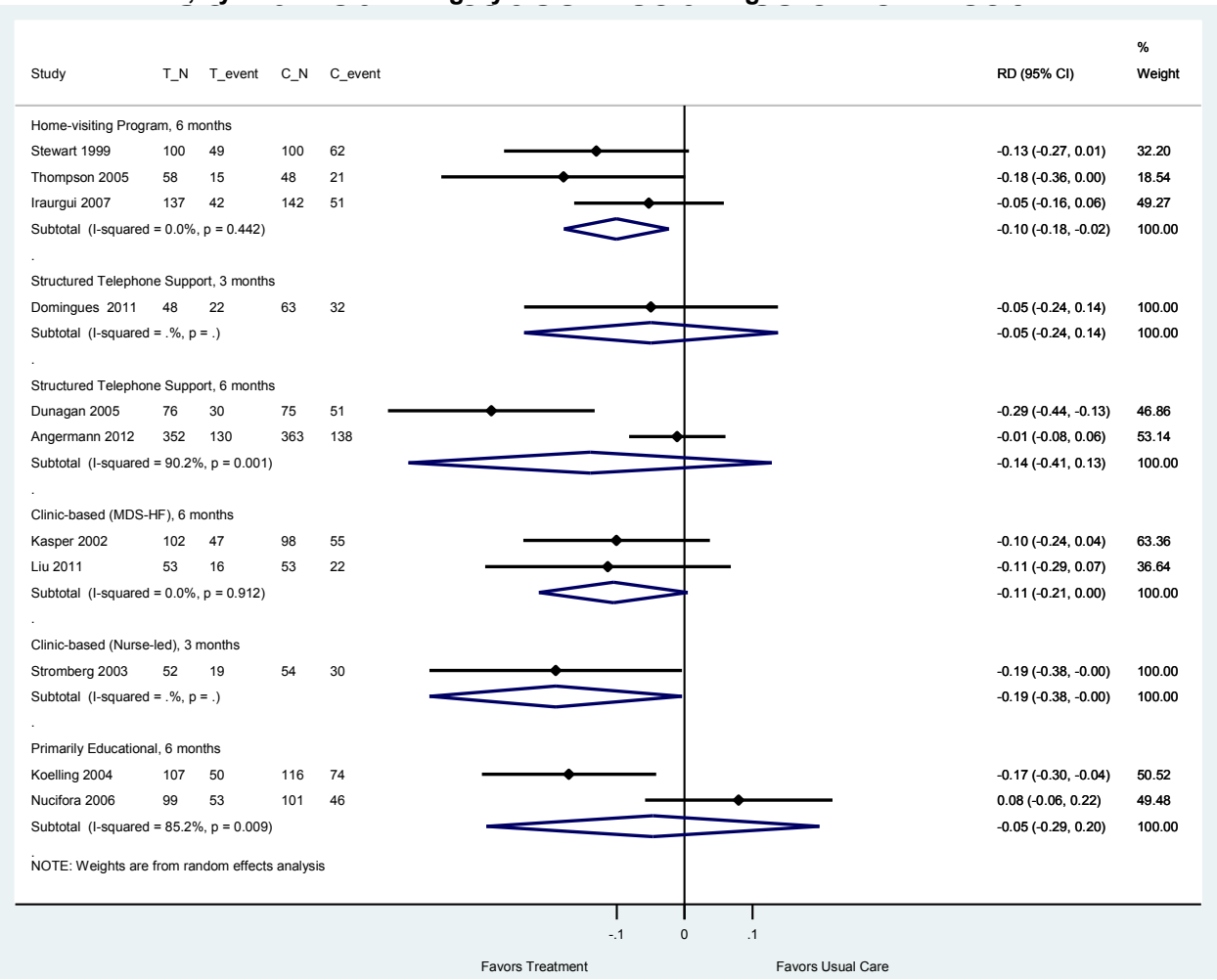
Other Interventions

One trial (N=88) assessing peer support among patients recently discharged for HF (rated high risk-of-bias) found a higher HF readmission rate among the intervention group than among the control group at 30 days and 3 months; the authors stated that the differences were not statistically significant (p-value or CIs not reported).[92]

Combined All-cause Readmission or Death: Transitional Care Interventions Compared with Usual Care

A meta-analysis of trials reporting the combined outcome of all-cause readmission or death is shown in Figure 5. This outcome was less commonly reported than other readmission rates. Home-visiting programs reduced this combined outcome measure at 6 months. We present detailed results by intervention category and outcome timing below.

Figure 5. Combined all-cause readmission or death for transitional care interventions compared with usual care, by intervention category and outcome timing



Home-Visiting Programs

Our meta-analyses (three RCTs) found fewer all-cause readmissions or deaths in patients receiving home visits than those receiving usual care (RD, -0.10; 95% CI, -0.18 to 0.02).[46,52,56] One other trial (N=239) presents the estimated proportion of patients alive and with no hospital readmissions at various points after the intervention.[51] Patients in the intervention group were more likely to be alive with no hospitalizations than those receiving usual care at 30 days (hazard ratios 0.869 [standard error (SE) 0.033] versus 0.737 [0.041]), 3 months (0.071 [0.045] versus 0.558 [0.047]), and 6 months (0.600 [0.047] versus 0.444 [0.047]); p-values were not reported (NR).

Structured Telephone Support

At 3 months, one trial (N=111) found no difference in the number of patients with the combined outcome between those receiving STS and those receiving usual care (RD, -0.05; 95% CI, -0.24 to 0.14).[63] At 6 months, our meta-analysis (two trials) found no difference in the number of patients with this outcome between those receiving STS and controls (RD, -0.14; 95% CI, -0.41 to 0.13).[62,64]

Clinic-Based Interventions

One trial (N=106) found that 19 percent fewer patients receiving care in a nurse-led HF clinic experienced the combined outcome than did patients receiving usual care (RD, -0.19; 95% CI, -0.38 to -0.00).[84]

Our meta-analysis (two trials) showed that patients receiving MDS outpatient care did not differ from patients receiving usual care in the combined outcome (RD, -0.11; 95% CI, -0.21 to 0.00).[83,86] One additional trial (N=106) found that 19 percent fewer patients receiving care in a nurse-led HF clinic experienced the combined outcome than patients receiving usual care (RD, -0.19; 95% CI, -0.38 to -0.00).[84]

Primarily Educational Interventions

Our meta-analysis (two trials) found no difference in the rate of all-cause readmission or death between patients receiving an educational intervention and patients receiving usual care (RD, -0.05; 95% CI, -0.29 to 0.20).[89,91]

Emergency Room or Acute Care Visits: Transitional Care Interventions Compared with Usual Care

Few trials reported on the number of patients seeking emergency care or acute care visits. All trials categorized these visits as "emergency department" or ER visits, we found no trials reporting acute care visits separately.

Home-Visiting Program

Three home-visiting trials reported on ER visits; all reported on different lengths of followup and used different methods to calculate the rate of ER visits. One trial (N=179) found that the number of patients who had an ER visit did not differ between those receiving home visits and those receiving usual care at 30 days (5 percent versus 4 percent, p-value NR) and at 3 months (17 percent versus 22 percent, p-value NR).[43] At 6 months, one trial (N=97) found fewer total ER visits per group among patients receiving home visits than among those receiving usual care (48 versus 87 visits, p=0.05).[47] One trial (N=58), rated high risk of bias, found no difference in

mean ER visits per patient over 6 months between patients in the intervention and control groups.[48]

Structured Telephone Support

At 3 months, one trial (N=111) found no difference in the total number of ER visits among patients receiving STS compared with patients receiving usual care (RR, 0.66; 95% CI, 0.21 to 2.05; p 0.67).[63] Two trials reported on the number of ER visits at 6 months; neither found a difference in ER visits among patients receiving STS and those receiving usual care. In one trial (N=276), 22.1 percent of patients receiving STS and 27.9 percent of patients receiving usual care had at least one ER visit (p=0.266).[70] Another trial (N= 358) reported the mean number of ER visits per person in each group; those receiving STS had 0.14 visits (standard deviation [SD], 0.45) and those receiving usual care had 0.11 visits (SD, 0.34) (p=0.58).[59] One trial (N=37), rated high risk of bias, found that patients receiving STS had fewer CHF-related ER visits over 6 months than controls; however, no difference was found in the number of all-cause ER visits between the intervention and control group.[68]

Telemonitoring

No trial assessing a telemonitoring intervention found either an increase or a decrease in ER visits in patients receiving the intervention compared with those receiving usual care. At 3 months in one trial (N=102), the average number of ER visits per patient did not differ between the telemonitoring group (0.34) and the control group (0.38) (p=0.73).[74] Two trials rated high risk of bias did not find a difference in total ER visits between patients receiving telemonitoring and those receiving usual care at 3 months.[68,77]

At 6 months, one trial (N=182) found that the total number of ER visits was lower in the intervention group (20) than in the control group (32); the authors stated that the difference was not significant (NS).[76] The authors of one trial (N=280, rated high risk of bias) reported no difference in ER visits between intervention and control groups at 6 months (data not provided).[75] One trial (N=37), rated high risk of bias, found that patients receiving telemonitoring had fewer CHF-related ER visits over 6 months than controls; however, no difference was found in the number of all-cause ER visits between the intervention and control group.[68]

Clinic-Based Interventions

In one trial (N= 230), at 6 months, the number of patients seen in the ER did not differ between patients receiving MDS-HF clinic management and those receiving usual care (HR, 0.97; 95% CI, 0.70 to 1.36).[85]

Primarily Educational Interventions

One trial (N=76) found that the number of patients seen in the ER did not differ between patients receiving video HF education and those receiving usual care at 3 months (38 percent of patients versus 33 percent; p=0.68).[88]

Hospital Days (of Subsequent Readmissions): Transitional Care Interventions Compared with Usual Care

Home-Visiting Programs

At 30 days, one trial (N=179) found no difference in the mean number of readmission hospital days between patients receiving home visits (2.2 days; SD, 7) and those receiving usual care (2.3 days; SD, 7).[43]

Our meta-analysis (four trials; see Appendix E) found no difference in the mean number of hospital days per person accumulated over 3 months between people receiving home visits and those receiving usual care (WMD, -1.17; 95% CI, -2.44 to 0.09).[43,49,53,54] At 6 months, three trials reported the total number of hospital days accumulated per group (along with a p-value). All found that patients receiving home visits accumulated fewer readmission days than controls (Table 10).

Table 10. Hospital days accumulated over 6 months: home visiting versus usual care

Author, Year	Sample size	Home Visiting Hospital Days	Usual Care Hospital Days	p-value
Stewart et al., 1998[47]	Home visiting (49) Usual care (48)	261	452	0.05
Stewart et al., 1999[46]	Home visiting (100) Usual care (100)	875	1476	0.04[a]
Thompson et al., 2004[56]	Home visiting (58) Usual care (48)	108	459	<0.01[b]

[a] Excluding "planned" admissions (e.g., for surgical procedures, other planned admissions).

[b] Adjusted for the number of events per patient per month of followup.

Structured Telephone Support

At 30 days, one trial (N=134) found no difference in the mean hospital days accumulated between patients receiving STS and controls (WMD, -0.95; 95% CI, -2.43 to 0.53).[60]

Our meta-analysis (four trials; Appendix E) found that patients receiving STS accumulated fewer total hospital days over 2 to 3 months than did patients receiving usual care (WMD, -1.43; 95% CI, -2.35 to -0.51).[59-61,71] Similarly, at 6 months, our meta-analysis (four trials; Appendix E) found that patients receiving STS accumulated fewer total hospital days than controls (WMD, -2.42; 95% CI, -4.44 to -0.39).[59,60,70,71]

Telemonitoring

No RCTs comparing telemonitoring with usual care found a reduction in length of hospital stay or total accumulated hospital days at any time point.

One trial (N=168) found no difference in mean length of hospital stay per patient readmitted both at 30 days (telemonitoring, 1.9 days [SD, 4.4]; control: 1.8 days [SD, 12.2]) or at 90 days (telemonitoring: 4.9 days [SD, 8.2]; usual care: 4.8 [SD, 10.2].[78] Another trial (N=121), rated high risk of bias, found no difference in mean length of hospital stay per person readmitted among patients receiving telemonitoring and controls (2.69 days versus 3.75 days; NS per authors).[77]

At 6 months, one trial (N=182) found no statistically significant difference in median duration of readmission hospital stay between intervention and control groups (17 days versus 13

days; p=0.99).[76] Two trials rated high[68] and unclear risk of bias[73] each found no difference in mean length of hospital stay at 6 months between the two arms of their studies.

Clinic-Based Interventions

At 3 months, one trial (N=106) found that patients receiving care in a nurse-led HF clinic had fewer hospital days per group than patients receiving usual care (350 days versus 592; p=0.045).[84] At 6 months, another trial (N=158) assessing a nurse-led intervention found no difference in mean hospital days per patient among patients receiving the intervention (26 days; SD, 31) and those receiving usual care (18 days; SD, 19) (p-value NS per investigators).[79]

One trial (N=230) found that patients receiving MDS-HF management had fewer total hospital days at 6 months than did patients receiving usual care (HR, 0.61; 95% CI, 0.39 to 0.95).[85]

One trial (N=443) evaluating increased access to primary care in a VA setting found that patients receiving the primary care intervention had a high mean hospital length of stay at 6 months compared with patients receiving usual care (9.1 versus 7.3 days; p=0.04).[87]

Primarily Educational Interventions

One trial (N=200) found no difference in the mean length of hospital stay over 6 months for patients receiving intensive predischarge education and those receiving usual care (20 days versus 15 days; p=NS per authors).[89]

Other Interventions

One trial (N=88; rated high risk of bias) assessing the efficacy of peer support for HF patients found no difference in the mean number of all-cause hospital days per patient among those receiving peer support and patients receiving usual care at 30 days (0.87 days versus 1.2 days; p=NS per authors) and at 3 months (1.8 days versus 2.1 days, respectively; p=NS per authors).[92]

Detailed Synthesis

Comparative Effectiveness of Transitional Care Interventions

Telemonitoring Versus Home Visiting

We identified one trial (N= 216, rated unclear risk-of-bias) that compared a telemonitoring with a home-visiting program. At 3 months, there were fewer total HF readmissions in the telmonitoring group compared to the group receiving home visits (13 versus 24 readmissions; p≤0.001).[57] Similarly, there were also fewer HF readmissions at 6 months in the telemonitoring group compared with the group receiving home visits (38 versus 63 readmissions; p≤0.05).[57] The group receiving telemonitoring accumulated fewer hospital days at 3 months than the group receiving home visits (49.5 versus 105.0 days; p≤0.001).[57]

Telemonitoring Versus Structured Telephone Support

One included RCT (N= 37), rated high risk of bias) included three arms: (1) telemonitoring (video nursing visits), (2) STS, and (3) usual care; no significant difference in all-cause or HF readmissions was observed between groups over 6 months.[68] Similarly, no difference was found

in mean ER visits or mean length of stay over 6 months between the telemonitoring and STS groups.[68]

KQ 2: Transitional Care Interventions and Health and Social Outcomes

Key Points: Mortality

- Both STS and MDS-HF clinic interventions were efficacious in reducing mortality at 6 months (both moderate SOE). STS did not reduce mortality at 2 to 3 months (moderate SOE); trials assessing MDS-HF clinic did not report mortality at earlier timepoints.
- At 30 days, home-visiting programs did not reduce mortality (low SOE).
- Two categories of interventions had no effect on mortality rates at 3 and 6 months: home-visiting programs (moderate SOE) and telemonitoring (low SOE).
- Evidence was insufficient on mortality outcomes for the following intervention categories: nurse-led HF clinic and primary care clinic interventions, primarily educational interventions, and cognitive training.

Key Points: Quality of Life and Function

- Home-visiting programs improved HF-specific quality of life (as measured by the Minnesota Living with HF Questionnaire) at 3 months (low SOE) but were not efficacious in improving quality of life at 6 months (low SOE).
- STS did not improve HF-specific quality of life at 3 or 6 months (low SOE).
- Primarily educational interventions did not improve quality of life at 6 months (low SOE).
- Evidence was insufficient on quality-of life-outcomes for telemonitoring at 3 months and clinic-based interventions MDS-HF clinic interventions at 6 months.
- Too few trials reported other quality-of-life outcomes or functional status outcomes using the same scales at similar timepoints to assess whether interventions improve general health-related quality of life or functional status.

Key Points: Caregiver and Self-Care Burden

- No trials assessing the efficacy of a transitional care intervention reported outcomes on caregiver or self-care burden.

Key Points: Comparative Effectiveness

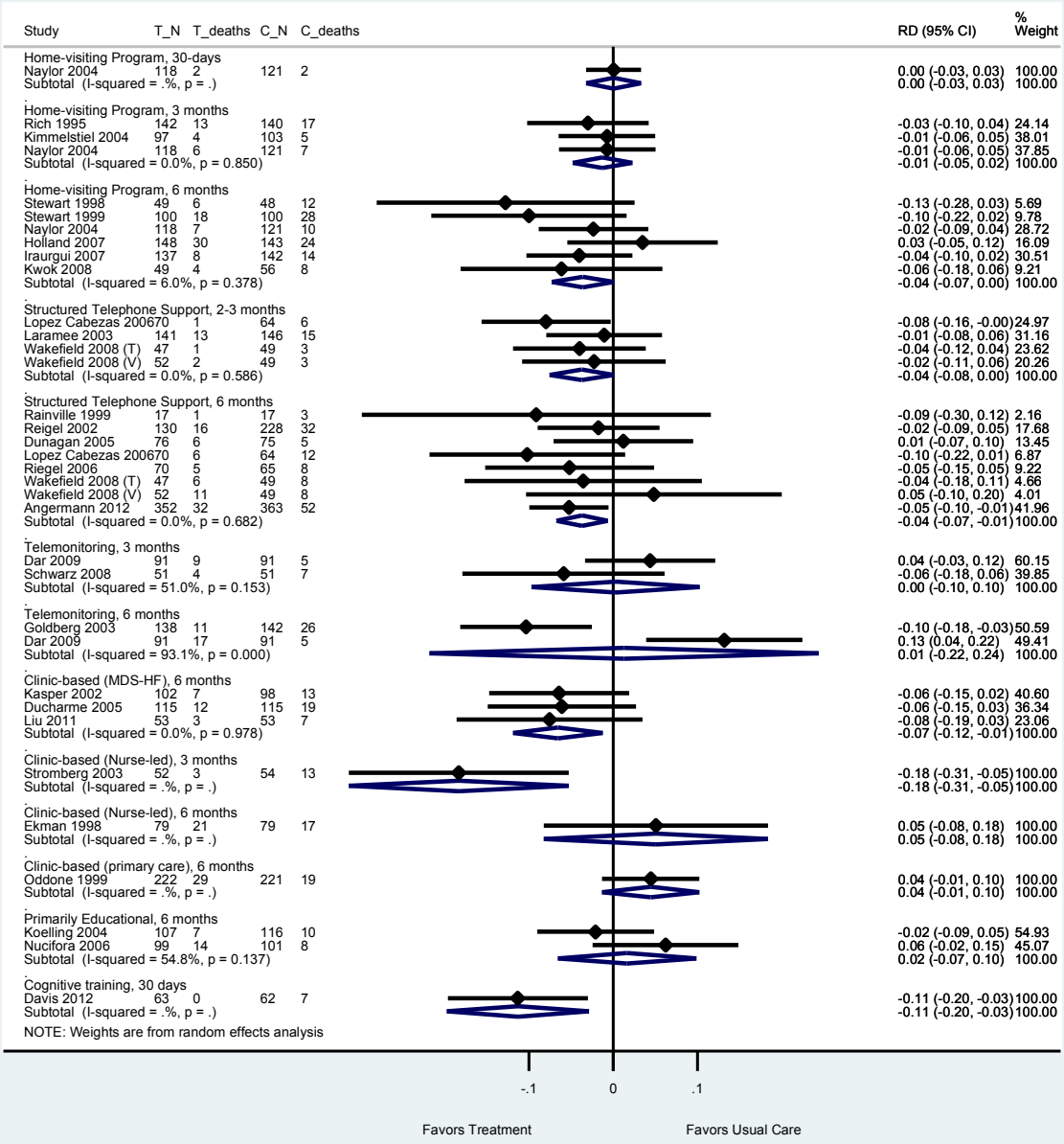
- Direct evidence was insufficient to determine whether one type of transitional care intervention is more or less efficacious than any other type of intervention for any health or social outcome.

Detailed Synthesis

Mortality: Transitional Care Interventions Versus Usual Care

Figure 6 presents our meta-analysis of trials reporting mortality stratified by intervention category and the outcomes measurement points. STS and MDS-HF clinic-based interventions reduced mortality over 6 months. We present detailed results by intervention category and outcome timing below.

Figure 6. Mortality among patients receiving transitional care interventions compared with usual care, by intervention category and outcome timing



Abbreviations: The study by Wakefield et.al includes two arms (two modes of STS): T= telephone; V=videophone.

Home-Visiting Programs

One trial (N=239) reported mortality rates at 30 days; there was no difference in mortality between the intervention and control groups (RD, 0.00; 95% CI, -0.03 to 0.03).[51] At 3 months, our meta-analysis (three trials) found that mortality did not differ among patients receiving home visits and those receiving usual care (RD, -0.01; 95% CI, -0.05to 0.02).[49,51,53] Similarly, at 6 months, our meta-analysis (six trials) found no difference in mortality between the intervention and control groups (RD, -0.04; 95% CI, -0.07 to 0.00).[46,47,50-52,55]

Structured Telephone Support

Our meta-analysis (three trials; the trial by Wakefield and colleagues contributes two comparisons) found no difference in mortality at 3 months between the intervention and control groups (RD, -0.04; 95% CI, -0.08 to 0.00).[61,65,71] At 6 months, our meta-analysis (seven trials; the trial by Wakefield and colleagues contributes two comparisons) found that 3.7 percent fewer patients receiving STS had died by 6 months than patients receiving usual care (RD, -0.04; 95% CI, -0.07 to -0.01).[59,60,62,64,65,69,71]

Telemonitoring

Our meta-analysis (two trials) found no difference in mortality at 3 months, between patients receiving STS and those receiving usual care (RD, -0.00; 95% CI, -0.10 to 0.10).[74,76] Similarly, our meta-analysis (two trials) found no difference in mortality at 6 months between the intervention and control groups (RD, 0.01; 95% CI, -0.22 to 0.24; I^2 93 percent).[75,76] These two trials produced inconsistent findings; one found a statistically significant increase in mortality among patients receiving telemonitoring compared with usual care,[76] and the other found a statistically significant reduction in mortality among patients receiving telemonitoring.[75] A sensitivity analysis, which included two additional trials rated as unclear or high risk of bias, did not change the overall results (Appendix E).

Clinic-Based Interventions

One trial (N=106) found that the group receiving care through a nurse-led HF clinic had 18 percent fewer deaths at 3 months than did controls (RD, -0.18; 95% CI, -0.31 to -0.05).[84]

Our meta-analysis (three trials) found that the MDS-HF clinic patients had 7 percent fewer deaths at 6 months than control patients (RD, -0.07; 95% CI, -0.12 to -0.01).[83,85,86] One trial of a nurse-led HF clinic found no difference in mortality at 6 months between patients receiving the intervention and patients receiving usual care (RD, -0.05; 95% CI, -0.08 to 0.18).[79] The trial assessing increased access to primary care (N= 443) found no difference in mortality between intervention and control patients at 6 months (RD, 0.04; 95% CI, -0.01 to 0.10).[87]

Primarily Educational Interventions

Our meta-analysis (two trials) found no difference in mortality between patients receiving an educational intervention and those receiving usual care (RD, 0.02; 95% CI, -0.07 to 0.10).[89,91]

Other Interventions

One trial assessing cognitive training among patients with HF and coexisting mild cognitive dysfunction found that the group receiving the intervention had 11 percent fewer deaths than patients receiving usual care (RD, -0.11; 95% CI, -0.20 to 0.03).[93]

Quality of Life or Function

Table 11 describes the common quality of life and functional status measures used in this literature. Overall, heterogeneity was considerable in the type of measure used across categories of interventions and at each eligible point of measuring outcomes. Few studies reported on measurements of functional status; for each category of interventions, we present our data synthesis of quality of life and functional status measures together.

Table 11. Quality of life or function measures used in the included trials

Abbreviated Name	Complete Name	Range of Scores	Improvement Indicated by
MLWHFQ	Minnesota Living with Heart Failure Questionnaire	0-105	Decrease
NYHA	New York Heart Association Classification	II-IV	Decrease
6MWT	Six Minute Walk Test	0-400+ meters[a]	Increase
EuroQoL or EQ-5D	European Quality of Life-5 Dimensions	0-100	Increase
SF-12	Medical Outcomes Study Self-Report Form (12-item)	0-100	Increase
SF-36	Medical Outcomes Study Short Form (36-items)	0-100	Increase

[a] This is the distance a person can walk within 6 minutes on a flat surface. An improvement of 54 meters is considered clinically significant.[95]

Home-Visiting Programs

Seven trials reported on at least one quality of life or functional status measure. One trial (N= 226) found that quality of life measured with the Minnesota Living with Heart Failure Questionnaire (MLWHFQ) did not differ between intervention and control groups at 2 weeks.[51] Our meta-analysis (two trials; Appendix E) found that patients receiving home visits had significantly better HF-specific quality of life than controls as measured by the MLWHFQ at 3 months (standardized mean difference [SMD], -0.26; 95% CI, -0.47 to -0.05).[51,55] One additional trial (N=200) found significant improvement in MLWHFQ scores at 3 months in patients receiving home visits compared with those receiving usual care (change from baseline: -19 versus -1; p=0.04).[46] At 6 months, however, our meta-analysis (2 trials; Appendix E) found no difference in quality of life between patients receiving home visits and controls (SMD, -0.04; 95% CI, -0.35 to 0.26).[51,55]

Table 12 summarizes the results of other quality of life or functional status measures reported by included trials assessing a home-visiting program. In one trial, patients receiving home visits had improved quality of life at 3 months as measured by the MLWHFQ and SF-36 physical health score.[46] Three additional trials found no improvement in any measure of quality of life or function at 3 or 6 months.

Two studies rated high risk of bias found no difference in function measured by the 6-minute walk test between patients receiving home visits and those receiving usual care; one measured function at 30 days[44] and the other at 6 months.[48]

Structured Telephone Support

Our meta-analysis (two trials; three comparisons; Appendix E) found no difference in MLWHFQ scores at 3 months among patients receiving STS and those receiving usual care (SMD, -0.21; 95% CI, -0.43 to 0.01) or at 6 months (SMD, -0.24; 95% CI, -0.56 to 0.08).[60,65] The trial by Wakefield and colleagues includes STS delivered by standard telephone and also by videophone (without telemonitoring); both STS modes were compared with usual care.[65]

Three additional trials reported on quality of life at 6 months; results are presented in Table 13. One trial found more people receiving STS had significantly better NYHA classification and SF-36 physical function and physical health scores at 3 months than patients receiving usual care.[62] Another reported on physical and emotional subscales of the MLWHFQ as well as physical and mental subscales of the SF-12; patients receiving STS had significantly better scores on the SF-12 physical scale than controls at 6 months, but all other comparisons were not significant.[64]

Table 12. Results of quality of life and function: Home-visiting versus usual care

Study	Arm (N)	Outcome Measures(s)	Baseline Value	Change from Baseline (or end of Treatment Mean)	P Value[a]
Stewart et al., 1999[46]	HV (100)	MLWHFQ	HV: 65 (47 to 70) UC: 62 (49 to 73)	3 months (median change and IQR): HV: -19 (-41 to 1); UC: -1 (-29 to 10)	0.04
	UC (100)			6 months: HV: -17 (-35 to -8); UC: -12 (-35 to -8)	0.30
		SF-36 physical health score	HV: 26 (21 to 32) UC: 23 (18 to 28)	3 months: HV: 16 (5 to 2.7); UC: 3 (-8 to 14)	0.02
				6 months : HV: 17 (3 to 27); UC: 15 (3 to 31)	0.53
		SF-36 mental health score	HV: 58 (48 to 76) UC: 56 (37 to 68)	3 months : HV: 10 (-19 to 19); UC: 6 (-9 to 31)	0.48
				6 months: HV: 7 (-15 to 31); UC: 19 (10 to 31)	0.46
Holland et al., 2007[55]	HV (148) UC (143)	EQ-5D	HV: 0.58 (SD 0.32) UC: 0.57 (SD 0.34)	3 months (Mean score and SD): HV: 0.54 (0.33); UC: 0.51 (0.37)	NS
				6 months: HV: 0.58 (0.29); UC: 0.52 (0.34)	0.07
Thompson et al., 2005[56]	HV (58) UC (48)	MLWHFQ	NR	6 months (change from baseline): HV: -14.2; UC: -13.7	NS
		SF-36	NR	SF-36 (change from baseline for 8 sub-scores; authors presented data in figure only)	NS
Kwok et al., 2008[50]	HV (44) UC (46)	6MWT	HV: 120.7 m (SD 62.0) UC: 118.5 m (SD 62.5)	6 months (changes in from baseline): HV: 44 (-15, 84) UC: 25 (-22, 69)	NS

[a] p-value is for result indicated- either change from baseline or difference in mean scores.

Abbreviations: HV = home visiting; IQR = interquartile range; MLWHFQ = Minnesota Living with Heart Failure Questionnaire; 6MWT = 6-minute walk test; NR = not reported; NS = not significant; SD, standard deviation; SF-36= Medical Outcomes Study Short Form (36 items); UC = usual care.

Table 13. Results of quality of life and function: Home-visiting versus usual care

Study	Arm (N)	Outcome Measures(s)	Baseline Value	Change from Baseline (or End of Treatment Mean)	P Value[a]
Angermann et al., 2012[62]	STS (352) UC (363)	NYHA class	% with NYHA III or IV: STS 40% UC 36%	NYHA class at 3 months Worsened: HV 17%; UC 10% Unchanged: HV 49%; UC 52% Improved: HV 33%; UC 38%	0.05[b]
		SF-36	STS: mean (SD) Physical function.: 48 (30) Physical health: 36 (11) Mental health: 44 (12) UC: mean (SD) Physical function.: 44 (29) Physical health: 36 (11) Mental health: 44 (12)	Mean change (SD) at 3 months Physical function: STS: +2.8 (10.0); UC +1.3 (9.9) Physical health: STS: +5.9 (25.8); UC +1.8 (24.7) Mental health: STS: +2.3 (12.4); UC +2.3 (12)	0.03 0.03 0.57
Lopez Cabezas et al., 2006[71]	STS (70) UC (64)	EuroQoL	NR	2 months: mean (SD) STS: 62.3 (17.3) UC: 65.0 (17.6) 6 months: mean (SD) STS: 62.9 (14.9) UC: 62.8 (14.1)	NS[b] NS[b]
Dunagan et al., 2005[64]	STS (64) UC (66)	MLWHFQ SF-12	Mean (SD) MLWHFQ physical scale: STS: 23.6 (10.8); UC: 23.0 (11.3) MLWHFQ emotional scale: STS: 46.2 (11.9); UC:46.6 (11.2) SF-12 physical scale: STS: 24.1 (10.1); UC: 24.9 (11.3) SF-12 mental scale: STS: 46.2 (11.9); UC: 46.6 (11.2)	Change from baseline (SD) at 6 months MLWHFQ physical scale: STS: 9.3 (8.9); UC: 5.2 (10.4) MLWHFQ emotional scale: STS: 2.7 (6.0); UC:2.4 (6.8) SF-12 physical scale: STS: 1.2 (9.9); UC: -2.7 (10.7) SF12 mental scale: STS: 7.3 (12.7); UC: 5.5 (11.7)	 0.33 0.90 0.028 0.20
Barth, 2001[58]	STS (17) UC (17)	MLWHFQ	MLWHFQ total score: STS: 50.9 (16.3); UC; 49.7 (15.7)	Change from baseline (SD) at 2 months: STS: 8.2 (4.3); UC: NR (NS per authors)	NR[c]

[a] All p-values in this column are for the difference in change from baseline between groups unless noted otherwise.

[b] p-value for overall trend (improvement) is based on logistic regression.[62]

[c] As reported by authors. The authors did not specifically report a p-value for the difference in mean change at 2 months between intervention and control groups. They did, however, report that the change from baseline to 2 months was p<0.00 for change from baseline (improvement) in STS group and "not significant" for the usual care group.

Abbreviations: MLWHFQ = Minnesota Living with Heart Failure Questionnaire; NR = not reported; NS = not significant; NYHA = New York Heart Association Classification; SD = standard deviation; SF-12 = Medical Outcomes Study Short Form (12-items); STS = structured telephone support; UC = usual care.

Telemonitoring

One trial (N=102) reported that patients receiving telemonitoring and those receiving usual care did not differ in mean MLWHF scores at 3 months (27.4 versus 27.3 respectively, p=0.99 for difference in mean scores between groups).[74] Another trial (N=182) reported no difference in MLWHFQ or European Quality of Life-5 Dimensions outcomes at 6 months between intervention and control groups (authors did not provide data).[76]

Clinic-Based Interventions

At 6 months, one trial (N=200) found that patients receiving care through an MDS-HF specialty clinic experienced significantly greater improvement on the total MLWHFQ score than did patients receiving usual care (change from baseline -28.3 versus -15.7; p=0.01).[83] In the same trial, patients receiving care in the MDS-HF clinic also experienced significantly greater improvement in NYHA functional class than did controls (25 percent of intervention group and 43 percent of the usual care group had NYHA class III or IV at 6 months; p=0.03 [test for trend]).[83]

The one trial (N=443) assessing enhanced access to primary found no difference between intervention and control groups in mean scores on the SF-36 mental and physical components at 6 months (p=0.2 for both subscores).[87]

Primarily Educational

Two trials evaluating a primarily educational intervention reported quality of life measured with the MLWHFQ at 6 months. One trial (N=223) found an improvement in total MLWHFQ score among patients receiving predischarge, in-person education compared with those receiving usual care (14 [SD, 20] versus 10 [SD, 16]; p<0.0001].[89] Another (N=149) found no improvement for patients receiving discharge education compared with usual care (41 [SD, 22] versus 42 [SD, 25]; p-value not reported).[91]

Other Interventions

Neither trial included in this category reported on a quality of life or functional status outcome.

Detailed Synthesis

Comparative Effectiveness of Transitional Care Interventions

Telemonitoring Compared With Home-visiting Program

One trial (N=216, rated unclear risk of bias) compared a telemonitoring program with a home-visiting program. MLWHF scores did not differ between patients receiving telemonitoring and patients receiving home visits at 3 months (telemonitoring mean score: 51.64 [SD, 17.36]; home-visiting mean score: 57.72 [SD, 16.24]; p=0.47).[57]

KQ 3. Components of Effective Interventions

We defined effective interventions as: (1) intervention categories (defined in Table 2 in Methods) that reduced all-cause readmissions (from our meta-analyses for KQ 1) or the combined endpoint of all-cause readmission or death; (2) intervention categories that reduced

mortality in in our meta-analyses; (3) individual trials in other categories that were efficacious for reducing all-cause readmissions, mortality or the combined endpoint. Few studies reported outcomes at 30 days; below we describe the components of interventions that showed efficacy at any eligible time point (up to 6 months following an index hospitalization for HF).

For all included trials, we abstracted information about the intervention components as the authors had described them. We considered intervention "components" as any part of the intervention that could be separated out and that could influence efficacy. Here we focus on the content (e.g., education, exercise recommendations) and process (e.g., care coordination) components of interventions. We evaluate intensity, delivery personnel, and mode of delivery separately in KQ 4; we also mention mode of delivery (e.g., whether the intervention is delivered in-person) because we cannot separate mode of delivery from some intervention components (e.g., use of home visits or coordination of care with providers). Across studies, authors provided varying levels of detail about interventions and components. The full data abstraction of intervention components of all included trials is shown in the evidence tables (Appendix C).

KQ 3a. Intervention Components

All-Cause Readmissions and Combined All-Cause Readmission or Death

Components of efficacious interventions in reducing all-cause readmissions are summarized in Table 14. In KQ 1, two categories of interventions were efficacious in reducing all-cause readmissions: home-visiting programs (3, 6 months) and MDS-HF clinic interventions (6 months). Two additional trials of STS showed efficacy at 6 months.[64,71] For the combined endpoint, home-visiting programs showed efficacy at 6 months. One additional trial assessing a home-visiting program found efficacy at 30 days as well as at 3 and 6 months.[51] Among other categories of interventions, one trial evaluating a 1-hour, face-to-face inpatient nursing education session showed a reduction in the combined endpoint at 6 months.[91]

Table 14. KQ 3 Components of effective interventions: All-cause readmissions

Author, year	Category	Primary Mode of Delivery	Self-management Promotion	Weight-monitoring Education	Diet/Sodium Restriction Education	Promotion of Medication Adherence	Exercise Education or Promotion	Unspecified HF Education	Medication Reconciliation
Liu, 2012[86]	MDS-HF	Face-to-Face	x			x			x
Ducharme, 2005[85]	MDS-HF	Face-to-Face	x	x	x	x		x	x
Kwok, 2007[50]	HV	Face-to-Face	x		x	x	x		x
Holland, 2007[55]	HV	Face-to-Face	x	x	x	x	x	x	x
Naylor, 2004[51]	HV	Face-to-Face	x	x	x	x			x
Jaarsma, 1999[43]	HV	Face-to-Face	x		x	x		x	
Aldamiz-Echevarría Iraúrgui, 2007[52]	HV	Face-to-Face	x	x	x	x		x	x
Thompson, 2005[56]	HV	Face-to-Face	x	x	x	x	x	x	x
Stewart, 1999[46]	HV	Face-to-Face	x	x		x	x		
Stewart, 1998[47]	HV	Face-to-Face	x			x			
Rich, 1995[53]	HV	Face-to-Face	x	x	x	x		x	x
Kimmelstiel, 2004[49]	HV	Face-to-Face	x	x	x	x		x	
Rich, 1993[54]	HV	Face-to-Face	x	x	x	x		x	x
Dunagan, 2005[64]	STS	Tele.	x	x	x	x	x		x
Lopez Cabezas, 2006[71]	STS	Tele.			x	x		x	
Koelling, 2004[91]	Edu.	Face-to-Face	x	x	x	x	x		

Table 14. KQ 3 Components of effective interventions: All-cause readmissions (continued)

Author, Year	Setting/ Timing of Education (Pre-d/c, Post-d/c or Both)	Transition Coach/Case Management*	Coordination w/ Outpatient Provider While Inpatient	Indivi-dualized Discharge Plan	Planned Telephone Followup Post Discharge	Timing of First Phone Follow-up (Days)	Series of Sche-duled Calls	Patient Hotline	Timing of First Home Visit (Days)	Number of Scheduled Home Visits	Medication Reconci-liation During Home Visit
Liu, 2012[86]	both	x		x	x	≤ 7	x	x	NA	NA	NA
Ducharme, 2005[85]	post-d/c				x	≤ 3	x		NA	NA	NA
Kwok, 2007[50]	both	x						x	< 7	6	x
Holland, 2007[55]	post-d/c								< 14	2	x
Naylor, 2004[51]	both	x	x	x				x	< 1	8	x
Jaarsma, 1999[43]	both			x	x	≤ 7		x	< 7	1	
Aldamiz-Echevarría Iraúrgui, 2007[52]	post-d/c							x	< 2	2 to 3	x
Thompson, 2005[56]	both	x						x	> 7	1	
Stewart, 1999[46]	post-d/c	x							> 7	1	
Stewart, 1998[47]	both	x							< 7	1	x
Rich, 1995[53]	both	x	x	x	as needed		x	<2	>3	x	x
Kimmelstiel, 2004[49]	post-d/c						x	x	<7	1	x
Rich, 1993[54]	both	x	x	x	as needed		x	<7	>3	x	x
Dunagan, 2005[64]	post-d/c				x	≤ 7	x	x			
Lopez Cabezas, 2006[71]	both				x	> 7	x	x	NA	NA	NA
Koelling, 2004[91]	pre-d/c									NA	NA

Table 14. KQ 3 Components of effective interventions: All-cause readmissions (continued)

Author, year	Unspecified HF Education/ Promotion During Home Visit	Symptom Checklist or Clinical Assessment During Home Visit *(e.g. History, Symptoms)*	Physical Exam During Home Visit	Home Visiting Personnel Coordinates Care or Collaborates With Outpatient Provider	Timing of First Clinic Visit Post Discharge (Days)	Consultation With a Dietician	Clinic Personnel on-Call/ Available for Acute Symptom Management *(Outside of Scheduled Appt)*	Clinical Pharmacist Visit/ Consultation	Medication Optimization; Predischarge or During Intervention
Liu, 2012[86]					≤ 7	x	x		x
Ducharme, 2005[85]					≤ 14	x	x	x	x
Kwok, 2007[50]		x	x	x	unclear				x
Holland, 2007[55]	x	x		x					x
Naylor, 2004[51]	x	x		x					
Jaarsma, 1999[43]	x								
Aldamiz-Echevarría Iraúrgui, 2007[52]	x	x	x						x
Thompson, 2005[56]	x	x	x				x		x
Stewart, 1999[46]	x	x	x	x					
Stewart, 1998[47]	x			x					
Rich, 1995[53]	x		x						x
Kimmelstiel, 2004[49]	x	x		x					
Rich, 1993[54]	x		x						x
Dunagan, 2005[64]									
Lopez Cabezas, 2006[71]					≥ 14			x	x
Koelling, 2004[91]									

Abbreviations: appt = appointment; d/c = discharge; Edu. = primarily educational; HV= home visits; MDS-HF = multidisciplinary heart failure; MDS = multidisciplinary; Med = Medium; STS = Structured Telephone Support; Tele. = Telephone; UC = usual care.

Shared Components of Home-visiting and MDS Clinic Interventions

Both home-visiting programs and MDS-clinic interventions are multicomponent, complex interventions. We found no single-component intervention (including predischarge only) that reduced all-cause readmissions. As a whole, these two categories of interventions shared the following components:

- HF education, emphasizing self-care, recognition of symptoms, and weight monitoring.
- HF pharmacotherapy emphasizing patient education about medications; promotion of adherence to medication regimens; promotion of evidence-based HF pharmacotherapy before discharge or during followup (or both).
- Face-to-face contact following discharge: via home-visiting personnel, MDS-HF clinic personnel, or both. In most cases, this contact occurred within 7 days of discharge.
- Streamlined mechanisms to contact care delivery personal (clinic personnel or visiting nurses or pharmacists) outside of scheduled visits (e.g., patient hotline).
- Mechanisms for postdischarge medication adjustment. In most cases, home-visiting personnel either directly recommended medication adjustment or assisted with coordination of care (e.g., with primary care provider or cardiologist) to facilitate timely medication adjustment, based on a patient's needs (rather than advising patients to call for help themselves).

Components of Individual Studies in Other Categories That Were Effective

In addition to trials assessing home-visiting programs and multidisciplinary clinic interventions, we identified two STS trials that reduced all-cause readmissions (Lopez Cabezas et al., 2006 and Dunagan et al., 2005) and one trial assessing a primarily educational intervention that reduced the combined endpoint all-cause readmission or death (Koelling et al., 2005).[64,71,91] Components of these interventions are shown in Table 14.

All three include a face-to-face inpatient education session before hospital discharge.[64,71,91] The one trial assessing an inpatient-only educational session included an hour-long visit with a nurse educator that focused on the following: mechanism of action of HF medications, specific guidance on sodium and water restriction, and comprehensive guidance on self-care behaviors (e.g., daily weight monitoring, smoking cessation, actions to take if symptoms worsened). In addition to the teaching session, patients receiving the intervention were given written guidelines in layman's terms.[91]

The two other efficacious interventions featured STS as the primary intervention;[64,71] these studies also included the following components:

- Comprehensive education (delivered face-to-face) before hospital discharge.
- Promotion of medication adherence during scheduled calls.
- A patient hotline for questions or advice outside of scheduled calls.
- The intervention by Dunagan and colleagues also included the following components: nurse-directed diuretic adjustment during telephone followup; flexibility of intervention based on patient need (e.g., 24 percent of patients received at least one home visit, and 24 percent were provided with a home bathroom scale).[64]

Mortality

We found a wider range of intervention types that reduced mortality (compared with the types of interventions that improved all-cause readmissions) within 6 months following an index hospital admission. Components of interventions that reduced mortality are summarized in Table 15. Although home-visiting programs were showed efficacy for reducing all-cause readmissions, we saw a trend toward improved mortality that was not statistically significant (RD, -0.04; 95% CI, -0.09 to 0.01; Appendix E).

Shared Components of Structured Telephone Support and MDS Clinic Interventions

Both STS and MDS clinic interventions are multicomponent. As a whole, these two categories of interventions shared the following components:

- HF education, emphasizing self-care, recognition of symptoms, and weight monitoring.
- A series of scheduled, structured visits (via telephone or clinic followup) that focused on reinforcement of education and monitoring for HF symptoms.
- A mechanism to contact providers easily outside of scheduled visits (e.g., patient hotline).

Components of Individual Studies in Other Categories That Were Effective

Three trials from other categories showed efficacy in reducing mortality: one telemonitoring trial,[75] one study of cognitive training in HF patients with cognitive dysfunction,[93] and one nurse-led HF clinic intervention.[84] These intervention types are heterogeneous; each involved a different set of intervention components. However, they all focused on transitioning self-care back to the patient, through giving inpatient education training on self-care management,[93] implementing a series of nurse-led clinic visits featuring self-care education, training and monitoring,[84] or encouraging daily weights and response to symptom questions via telemonitoring.[75] To some degree, all three interventions involved flexibility to individualize care (e.g., by coordinating with the patient's physician[75] or individualizing self-care training[84,93]). The one trial of telemonitoring that showed efficacy in reducing mortality specified that coordination of care with the patient's outpatient provider was a component of the intervention.[75]

KQ 3b. Necessity of Particular Components in Effective Interventions

Given the heterogeneity of interventions, we had insufficient detail across all interventions to determine whether certain components are necessary beyond what was addressed in KQ 3a. One intervention that reduced the combined outcome (all-cause readmission or death) was delivered during the index hospitalization, without any components delivered postdischarge).[91] In most cases, interventions that showed efficacy were delivered either both before and after discharge or in the postdischarge setting.

For all-cause readmissions (and the combined measure of all-cause readmission or death), several elements seem to be necessary: education focused on self-management (delivered face-to-face), early contact following discharge (e.g., home visit or outpatient followup), and flexibility in the intervention that allows tailoring the intervention to patient's needs (e.g., early adjustment of medications based on symptoms) and a mechanism for patients to contact intervention personnel easily for problems or symptoms (e.g., availability of a patient hotline).

Table 15. KQ 3 Components of effective interventions: Mortality

Author, year	Category	Primary Mode of Delivery	Self-management Education/ Promotion	Weight-Monitoring Education or Promotion	Diet/Sodium Restriction Education or Promotion	Promotion of Medication Adherence	Exercise Education or Promotion	Other or Unspecified HF Education	Medication Reconciliation
Kasper, 2002[79]	MDS-HF	Face-to-Face	x					x	
Liu, 2012[86]	MDS-HF	Face-to-Face	x			x			x
Ducharme, 2005[85]	MDS-HF	Face-to-Face	x	x	x	x		x	x
Reigel, 2002[59]	STS	Tele.	x		x	x		x	x
Rainville, 1999[69]	STS	Tele.		x		x		x	
Dunagan, 2005[64]	STS	Tele.	x	x	x	x	x		x
Lopez Cabezas, 2006[71]	STS	Tele.			x	x		x	
Riegel, 2006[60]	STS	Tele.	x		x	x		x	
Wakefield, 2008[65] Wakefield, 2009[66]	STS	Tele.	x	x	x	x			
Wakefield, 2008[65] Wakefield, 2009[66]	STS	Video-phone	x	x	x	x			
Angermann, 2011[62]	STS	Telephone	x	x	x	x	x	x	
Davis, 2012[93]	other	Face-to-Face	x	x	x	x			
Stromberg, 2003[84]	Clinic (nurse)	Face-to-Face	x	x	x	x			
Goldberg 2003[75]	TM	TM	x	x	x				

Table 15. KQ 3 Components of effective interventions: Mortality (continued)

Author, year	Setting/ Timing of Education (Pre-d/c, Post-d/c or Both)	Transition Coach or Coordination Between Inpatient/ Outpatient Providers	Planned Telephone Follow-up Post Discharge	Timing of First Phone or TM Followup (Days)	Phone Follow-up Conducted by Same Personnel Delivering Inpatient Intervention Component	Series of Structured Calls	Patient Hotline (*e.g. Patients Can Call Anytime for Help)*	Timing of First Clinic Visit Post Discharge	Consult with Nutritionist	Clinic Personnel On-call/ Available for Outside of Clinic Hours	Outpatient Clinical Pharmacist visit
Kasper, 2002[79]	x	x					x				
Liu, 2012[86]	both	x	x	≤ 7	Unclear	x	x	≤ 7	x	x	
Ducharme, 2005[85]	post-d/c		x	≤ 3		x		≤ 14	x	x	x
Reigel, 2002[59]	post-d/c		x	≤ 7		x					
Rainville, 1999[69]	both	x	x	≤ 2	x	x	x				
Dunagan, 2005[64]	post-d/c		x	≤ 7		x	x				
Lopez Cabezas, 2006[71]	both		x	> 7	x	x	x				x
Riegel, 2006[60]	post-d/c		x	≤ 7		x					
Wakefield, 2008[65] Wakefield, 2009[66]	both		x	≤ 7		x	x				
Wakefield, 2008[65]	both										
Angermann, 2011[62]	both	x	x	≤ 7	x	x	x				
Davis, 2012[93]	both		x	≤ 7	x						
Stromberg, 2003[84]	post-d/c							>14	x	x	x
Goldberg, 2003[75] [a]	pre-d/c										

[a] Telemonitoring components also included: first telehealth contact >7 days postdischarge, telemonitoring device included an automated adherence reminder, transmitted vital signs and symptoms, and service coordinated care with outpatient provider(s).

Abbreviations: d/c = discharge; HF = heart failure; MDS-HF = multidisciplinary heart failure; MDS = multidisciplinary; Med = Medium; Pharm = Pharmacist; STS = Structured Telephone Support; TM = telemonitoring.

For mortality, including training or reinforcement on self-care (e.g., daily weights) and reinforcing these skills over time both seem necessary. Like interventions that reduced all-cause readmissions, interventions that reduced mortality rates included instructions (or a patient hotline) on who and when to call when symptoms worsen.

KQ 3c. Benefits of Particular Components in Multicomponent Interventions

We did not find any direct evidence to determine whether specific components add benefit. That is, no trials directly compared the delivery of an intervention without a specific component with the same intervention including addition of a specific component. When attempting to use indirect evidence, the heterogeneity of components included in the interventions across categories (and within intervention categories) limited our ability to isolate specific factors that added benefit. Separating out individual components from the overall type (or "bundles") of interventions that showed efficacy (KQs 1 and 2) was not possible.

KQ 4. Intensity, Delivery Personnel, Method of Communication

To assess whether the efficacy of interventions varies based on intensity, delivery personnel or method of communication, we assessed variation both across and within intervention categories (when present). We did not pool trials in a meta-analysis from different intervention categories to assess the impact of intensity, delivery personnel, or method of communication because many other factors (e.g., different intervention components) differed too much across categories.

For the KQ 4 analyses, we used trials included in our main analyses for either of the two primary outcomes (all-cause readmissions and mortality)—i.e., trials rated as medium or low risk of bias. Appendix C (Tables C1-C12) describes the intensity, primary delivery personnel, and method of communication for these trials. For some categories of interventions, variation was insufficient within categories or we had too few trials to conduct any meaningful stratified analyses. These limitations differed by each subquestion (intensity, delivery personnel and method of communication); for each subquestion discussed below, we address only the intervention categories with sufficient variation or sufficient number of trials to assess whether efficacy differed by these factors.

Key Points: Intensity

- In general, intervention categories that included higher-intensity interventions (i.e., home-visiting programs, STS, MDS-HF clinic interventions) reduced all-cause readmissions or mortality. By contrast, categories with lower-intensity interventions (i.e., primarily educational interventions, nurse-led HF clinic interventions) were not efficacious.
- Within categories, evidence was generally insufficient to make definitive conclusions about whether higher or lower-intensity interventions are more or less efficacious for reducing all-cause readmissions or mortality. Subgroup analyses found that higher intensity home-visiting programs reduced all-cause readmission at 30 days while lower intensity programs did not (low SOE). No significant differences based on intensity were

found for STS interventions. Subgroup analyses were not possible for other categories of interventions because of either lack of variation or too few trials reporting outcomes at similar timepoints.

Key Points: Delivery Personnel

- The two categories of interventions that reduced all-cause readmissions and mortality—home-visiting programs and MDS-HF clinic interventions—were more likely to include teams of providers delivering the intervention (e.g., home visits conducted by a nurse and pharmacist together). For mortality, primary delivery personnel varied more among intervention categories that were efficacious than among those that were not; STS interventions, which were delivered primarily by nurses and pharmacists, were also efficacious.
- Within categories, evidence was insufficient to make definitive conclusions about whether specific delivery personnel had more (or less) impact reducing all-cause readmissions or mortality.

Key Points: Method of Communication

- Across intervention categories, interventions were delivered primarily face-to-face or via technology (telephone, telemonitoring, video visits). The two categories of interventions delivered primarily face-to-face did reduce all-cause readmissions—namely, home-visiting programs and MDS-HF clinic interventions. For these two categories, method of delivery did not vary within each category. STS showed efficacy in reducing mortality; some of these interventions included a face-to-face component (e.g., predischarge educational intervention). In general, interventions delivered primarily remotely (i.e., telemonitoring, STS) did not reduce all-cause readmissions.
- Only STS interventions varied in their method of communication; our subgroup analyses for reducing either all-cause readmissions or mortality found no significant differences by method of communication at any timepoint.

Detailed Synthesis

KQ 4a. Intensity

For most interventions, we defined intensity as the duration, frequency, or periodicity of patient contact, and we categorized each intervention as low, medium, or high intensity. Given the heterogeneity of intensity across included interventions, however, we were unable to develop a single measure of intensity that could be applied to studies across all intervention categories.

We also considered resource use as a dimension of intensity. For example, we included factors such as the total number of intervention components in the determination of intensity. We reserved the low-intensity category for interventions that included one episode of patient contact or that required few resources (e.g., no additional components, such as time spent coordinating care). We considered the majority of interventions to be of medium or high intensity; most were multicomponent and included repeated patient contacts.

Intensity Across Intervention Categories

The MDS-HF clinic interventions were all classified as high intensity. Two categories included no trials classified as high intensity: primarily educational interventions and trials in the "other" category. Trials involving home-visiting interventions and STS included a mix of medium- and high-intensity interventions. Overall, the home-visiting category included more trials classified as high intensity (five of six interventions) than the STS category (four of six).

Our meta-analysis (KQs 1 and 2) showed that trials involving higher-intensity interventions (i.e., home-visiting programs, STS, MDS-HF clinic interventions) reduced all-cause readmissions or mortality. By contrast, trials with lower-intensity intervention (i.e., primarily educational interventions, nurse-led HF clinic interventions) did not.

Intensity Within Intervention Categories

Home-Visiting Program

Table 16 displays the intensity, delivery personnel, and method of communication for the 11 trials that we rated as either low or medium risk of bias (listed in chronological order). All were multicomponent, relatively complex interventions. We used the number of home visits (one visit or a series of visits) and the inclusion of other components (e.g., predischarge educational session, individualized discharge planning) to determine whether interventions were of medium or high intensity. We determined that five were high intensity and six were medium intensity.

Table 16. Intensity, delivery personnel and method of communication in trials assessing home-visiting programs compared with usual care

Author, Year	Timing (Months)[a]	Intensity	Delivery Personnel	Method of Communication
Rich et al., 1993[54]	3	High	Multidisciplinary	Face-to-face
Rich et al., 1995[53]	3	High	Multidisciplinary	Face-to-face
Stewart et al., 1998[47]	6	Medium	Multidisciplinary	Face-to-face
Jaarsma et al., 1999[43]	1, 3	Medium	Nurse	Face-to-face
Stewart et al., 1999 [46]	6	Medium	Nurse	Face-to-face
Pugh et al., 2001[48]	6	Medium	Nurse	Face-to-face
Kimmelstiel et al., 2004[49]	3	Medium	Nurse	Face-to-face
Naylor et al., 2004[51]	1, 3, 6	High	Nurse	Face-to-face
Aldamiz-Echevarría Iraúrgui et al., 2007[52]	6	High	Multidisciplinary	Face-to-face
Holland et al., 2007[55]	6	Medium	Pharmacist	Face-to-face
Kwok et al., 2007[50]	6	High	Nurse	Face-to-face

[a] This is the timing of readmission outcomes.

All-Cause Readmissions

Eight trials of either low or medium risk of bias reported all-cause readmissions; among these, we rated five as high intensity[50-54] and three as medium intensity.[43,47,55] Our subgroup analyses for reduction in all-cause readmissions found that higher intensity home home-visiting programs reduced all-cause readmissions at 30 days while lower intensity interventions did not (Appendix E). This issue is also discussed in KQ 1. Our ability to make any definitive conclusions at other timepoints is limited by lack of precision; too few trials reported outcomes at the same timepoint to permit us to assess adequately whether efficacy of home-visiting programs differed by intensity.

Mortality

Eight medium or low risk-of-bias trials reported mortality, among these, we rated four as high intensity[50-53] and four as medium intensity.[46,47,49,55] Our subgroup analyses for reduction in mortality found no significant difference in intensity at any outcome timepoint (Appendix E). As with all-cause readmissions, however, diversity in measurement timepoints and lack of precision (wide and overlapping CIs) limited our ability to make any definitive conclusions.

Structured Telephone Support

Table 17 displays the intensity, delivery personnel, and method of communication for 10 trials that we rated as low or medium risk of bias. Among STS interventions, determining whether trials varied sufficiently in the periodicity or frequency of telephone support was difficult. Trials included similar numbers of planned telephone calls at each time point (e.g., weekly for 1 month following hospitalization, then bi-weekly for 2 months or 3 months). Often, interventions specified that calls could occur more frequently based on need or that a patient hotline was available for questions or concerning symptoms. Whether interventions included additional components other than STS also varied across these trials (e.g., intensive inpatient education). When interventions included STS and additional components that required face-to-face contact with patients or time spent coordination of care with a clinician in response to a patient's symptoms, we classified those interventions as high intensity (four trials).[61,62,64,70] We rated one trial as low intensity; it included a series of telephone calls (<8 per person over 3 months) with no other components (e.g., no care coordination or face-to-face contact).[63] The remaining interventions were considered medium intensity.

Table 17. Intensity, delivery personnel and method of communication in trials assessing structured telephone support compared with usual care

Author, Year	Timing (months)[a]	Intensity	Delivery Personnel	Method of Communication
Rainville et al., 1999 [69]	6	Medium	Pharmacist	Telephone; Face-to-face
Riegel et al., 2002[59]	3, 6	Medium	Nurse	Telephone
Laramee et al., 2003[61]	2	High	Non-nurse case-manager	Telephone; Face-to-face
Tsuyuki et al., 2004[70]	6	High	Nurse	Telephone
Dunagan et al., 2005[64]	6	High	Nurse	Telephone
Cabezas et al., 2006[71]	2, 6	Medium	Pharmacist	Telephone; Face-to-face
Riegel et al., 2006[60]	1, 3, 6	Medium	Nurse	Telephone
Wakefield et al., 2008[65] Wakefield et al., 2009[66]	6	Medium	Nurse	Group 1: Telephone Group 2: Videophone
Domingues et al., 2011[63]	3	Low	Nurse	Telephone
Angermann et al., 2012[62]	6	High	Nurse	Telephone; Face-to-face

[a] This is the timing of readmission outcomes.

All-Cause Readmissions

In KQ 1 we found that STS interventions had no efficacy in decreasing all-cause readmissions at any timepoint. Our analysis stratified by intensity found no significant difference between in high-intensity and medium-intensity trials at any point (Appendix E). Confidence intervals were wide and overlapped in all cases. One high-intensity trial reported a significant reduction in all-cause readmissions at 6 months (RD, -0.28; 95% CI, -0.44 to 0.13).[64] When stratified by intensity, only trials rated as medium intensity found statistically significant reductions in all-cause readmissions over 2 to 3 months (RD, -0.08; 95% CI, -0.16 to -0.01).[59,60,71]

Mortality

We found no significant difference in reducing mortality rates between high-intensity and medium-intensity trials at any timepoint (Appendix E). Confidence intervals were wide and overlapped in all cases.

Telemonitoring

Table 18 displays the intensity, delivery personnel, and method of communication for four trials that we rated low or medium risk of bias. Intensity varied little across these trials; two were considered high intensity (both reported all-cause readmissions at 6 months) and two were considered medium intensity (both reporting all-cause readmissions at 3 months). The two high-intensity trials involved additional components (other than remote monitoring alone); one used both video visits and remote monitoring,[76] and one included an individualized weight goal along with direct communication with a clinician when the patient fell outside of his or her normal weight range.[75] Intensity did not vary sufficiently at outcome measurement points to permit meaningful subgroup analysis.

Table 18. Intensity, delivery personnel and method of communication in trials assessing telemonitoring compared with usual care

Author, Year	Timing (months)[a]	Intensity	Delivery Personnel	Method of Communication
Goldberg et al., 2003[75]	6	High	Nurse	Remote monitoring
Schwarz et al., 2008[74]	3	Medium	Nurse	Remote monitoring
Dar et al., 2009[76]	6	High	Nurse	Remote monitoring
Pekmezaris et al., 2012[78]	1, 3	Medium	Nurse	Video visits

[a] This is the timing of readmission outcomes.

Clinic-Based Interventions

Given heterogeneity among the clinic-based interventions, we pooled data separately in KQ 1 and KQ 2 for MDS-HF clinic interventions, nurse-led HF clinic interventions, and primary care clinic interventions. These categories directly matched stratification by intensity, delivery personnel, and method of communication. Therefore, we did not conduct new analyses to stratify interventions by these factors.

In terms of intensity, we considered MDS-HF clinic interventions to be high intensity and the nurse-led and primary care interventions medium intensity. We determined intensity for the clinic-based interventions primarily on resource use (e.g., planned contact with multiple providers in a specialty clinic during each patient visit). The periodicity or frequency of clinic visits did not vary in any clear ways; most interventions increased clinic visit frequency based on a patient's need (i.e., they were tailored based on clinical status) in addition to planned visits.

All-Cause Readmissions

As described in KQ 1, high-intensity MDS-HF interventions reduced all-cause readmissions at 6 months (Figure 2); the medium-intensity nurse-led HF clinic[79] and the primary care clinic intervention[87] did not.

Mortality

As described in KQ 2, both the high-intensity MDS-HF interventions and one medium-intensity nurse-led HF intervention reduced mortality at 6 months and the medium-intensity primary care clinic based intervention did not (Figure 6).

Primarily Educational Interventions

Table 19 displays the intensity, delivery personnel, and method of communication for the two trials rated as low or medium risk of bias. Two primarily educational interventions reported mortality; we rated one as low intensity[91] and the other as medium intensity.[89] Both assessed inpatient educational interventions; the trial by Nucifora et al. included additional components (e.g., telephone contact following discharge to reinforce education).[89] One trial reported on all-cause readmissions; both reported mortality at 6 months.

Table 19. Intensity, delivery personnel and method of communication in trials assessing primarily educational interventions compared with usual care

Author, Year	Timing (ms)[a]	Intensity	Delivery Personnel	Method of Communication
Koelling et al., 2005[91]	6	Low	Nurse	Face-to-face
Nucifora et al., 2006[89]	6	Medium	Nurse	Face-to-face

[a] This is the timing of readmission outcomes.

Our meta-analysis of these two trials showed that neither intervention reduced mortality (Figure 6). Lack of precision (wide and overlapping CIs) and different lengths of followup limited our ability to draw definitive conclusions.

KQ 4b. Delivery Personnel

Delivery Personnel Across Intervention Categories

Most interventions were delivered primarily by nurses or MDS teams; a few home-visiting and STS interventions were delivered by pharmacists. The two categories of interventions that reduced all-cause readmissions (home-visiting; MDS-HF clinic) were more likely to use teams of providers to deliver the interventions (e.g., home visits conducted by a nurse and pharmacist together). For mortality, the efficacious intervention categories varied in primary delivery personnel. MDS-HF clinic interventions (delivered by MDS teams) and STS interventions (delivered primarily by nurses or pharmacists) both reduced mortality.

Delivery Personnel Within Intervention Categories

Home-Visiting Programs

Table 16 (above) listed the included studies and delivery personnel. When more than one delivery person was involved in a major intervention component, we considered home-visiting interventions to be MDS (e.g., physician accompanies nurse on home visit or adjusts medications before discharge). We considered four interventions to be delivered primarily by MDS teams.[47,52-54] One intervention was delivered by a pharmacist;[55] remainder of trials used interventions delivered primarily by nurses.

All-Cause Readmissions

Seven trials reported all-cause readmissions rates. Variation at 30 days and 3 months was insufficient to determine whether delivery personnel influenced reductions in all-cause readmissions; at 6 months, our subgroup analyses found no significant difference by delivery personnel (Appendix E). However, our ability to make definitive conclusions was limited by lack of precision and disparity in when outcomes were measured.

Mortality

Seven home-visiting trials reported mortality. Variation at 30 days and 3 months was insufficient to determine whether delivery personnel influenced reductions in mortality. At 6 months, our subgroup analysis found no significant differences by delivery personnel (Appendix E).

Structured Telephone Support

Table 17 (above) listed the included trials and delivery personnel. The majority of STS interventions were conducted by nurses; two interventions were conducted by a pharmacist[69,71] and one by a non-nurse case-manager.[61]

All-cause Readmissions

Our subgroup analyses for all-cause readmissions found no significant differences by delivery personnel (Appendix E). Delivery personnel did not vary much at each timepoint; confidence intervals were wide and overlapped. Overall, of 10 trials, two trials found a statistically significant reduction in all-cause readmissions; one intervention was delivered by a nurse[64] and one was delivered by a pharmacist.[71]

Mortality

Our subgroup analysis for mortality found no significant differences by delivery personnel (Appendix E). Delivery personnel varied little at each time-point and few trials reported outcomes at the same timepoint (Appendix E).

Clinic-based Interventions

As discussed above, given heterogeneity in the interventions among the clinic-based interventions, we pooled data separately by clinic setting for KQ 1 and KQ 2: MDS-HF clinic, nurse-led HF clinic, and primary care clinic. As was true for intensity, these groupings also reflect differences in delivery personnel. The MDS-HF interventions included a range of providers who had contact with patients during clinic visits. The nurse-led interventions primarily involved education and symptom monitoring delivered by nurses. The primary-care intervention involved increased access to a primary care clinic, including contact with a primary care physician and clinic nurse.

All-cause Readmissions

As described in KQ 1, the MDS-HF interventions did reduce all-cause readmissions at 6 months (Figure 6). Neither the nurse-led[79] nor the primary care intervention[87] was efficacious.

Mortality

As described in KQ 2, both the MDS-HF interventions and one of the nurse-led interventions reduced mortality at 6 months. The medium-intensity primary care intervention did not reduce mortality (Figure 6).

KQ 4c. Method of Communication

Method of Communication Across Intervention Categories

Across intervention categories, interventions were delivered primarily face-to-face or via technology (telephone, telemonitoring, video visits). Home-visiting programs and MDS-HF

interventions, which are delivered primarily face-to-face, reduced all-cause readmissions; for these two categories, method of delivery did not vary within each category. STS also reduced mortality; some of the STS interventions include a face-to-face component (e.g., predischarge educational intervention). In general, interventions primarily delivered remotely (i.e., telemonitoring, structured telephone support) were not efficacious in reducing all-cause readmissions.

Method of Communication Within Intervention Categories

Only STS interventions varied in their method of communication. Other categories did not differ materially in their primary method of communication.

Structured Telephone Support

STS interventions were delivered primarily via a series of structured calls to patients. Four STS interventions also had a face-to-face intervention (usually predischarge education).[61,62,69,71] Our subgroup analysis found no difference in efficacy for either all-cause readmissions or mortality among trials with a face-to-face component compared with those with primarily the telephone contact (Appendix E); confidence intervals were wide and overlapped. Our ability to make definitive conclusions was limited by lack of precision (wide, overlapping CIs) and dissimilar points for measuring outcomes.

One STS intervention directly compared two modes of delivery: standard telephone support and videophone (without telemonitoring technology), along with usual care. There was no difference in all-cause readmissions in the three groups at 3 and 6 months.[65]

KQ 5. Subgroups

This KQ evaluated whether transitional care interventions differ in either benefits or harms for subgroups of patients. For this question, we searched for subgroup analyses reported by individual studies that focused on whether a particular intervention had more (or less) efficacy in reducing readmissions or mortality based on patient age, sex, race, ethnicity, socioeconomic status, disease severity (left ventricular ejection fraction or NYHA classification), or coexisting conditions. Only two trials, one home-visiting program and one primarily educational intervention, reported readmission rates for subgroups. No other trials reported on readmissions by subgroups; no trial reported on mortality by subgroups.

Detailed Synthesis

Home-Visiting Programs

Rich and colleagues categorized patients as being at low, moderate, or high risk for readmission.[54] They used a combination of markers of disease severity and coexisting conditions: four or more prior hospitalizations within 5 years of randomization, previous history of HF, hypocholesterolemia (total cholesterol <150 mg/dL), and right bundle-branch block on the admitting electrocardiogram. Patients with none of these factors were considered low risk and excluded from the study; patients with one risk factor were considered moderate risk; those with two or more risk factors were considered to be at high risk for readmission. Among the moderate-risk subgroup, fewer people receiving home visits were readmitted than people not receiving home visits, but the difference was not statistically significant (27.5 percent versus 47.6 percent; p=0.10).[54] Among the high-risk subgroup, the percentage of patients readmitted

over 90 days did not differ between the intervention and control groups (43.5 percent versus 42.9 percent; p-value NS).[54]

Primarily Educational Interventions

One trial assessing a 1-hour, face-to-face inpatient educational session reported the relative risk of a combined endpoint—all-cause readmission or death at 6 months—for patient subgroups based on age, sex, race, or presence of coronary disease.[91] The p-values for risk ratios were not significant for each comparison (age $\geq$ 65 versus < 65; gender; black versus white race; presence versus absence of coronary disease).[91]

Discussion

For this report, we conducted a systematic review to evaluate the evidence for transitional care interventions for adults hospitalized for heart failure (HF). Below, we summarize the main findings and strength of evidence (SOE). We then discuss the findings in relation to what is already known, applicability of the findings, implications for decisionmaking, limitations, research gaps, and conclusions. When we have graded evidence as insufficient, the evidence is either unavailable, does not permit estimation of an effect, or does not permit us to draw a conclusion with at least a low level of confidence. An insufficient grade does not indicate that an intervention has been proven to lack efficacy.

Our main findings and conclusions are based on trials comparing transitional care interventions with usual care that we rated as low or medium risk of bias. We identified only two trials comparing one type of intervention with another (i.e., making head-to-head comparisons); both were rated as high risk of bias. Thus, direct evidence was insufficient to draw conclusions about comparative effectiveness.

Key Findings and Strength of Evidence

Efficacy for Reducing Readmissions and Mortality

HF is a leading cause of readmission among Medicare patients. As described in the introduction, the Centers for Medicare & Medicaid Services (CMS) implemented policies in 2012 that lower reimbursements to hospitals with excessive risk standardized 30-day readmission rates, creating incentives for hospitals to reduce 30-day readmission rates for people with HF. We found very little evidence on whether interventions reduce 30-day readmissions. Most studies reported rates over 3 or 6 months. One high intensity home-visiting trial showed efficacy in reducing 30-day all-cause readmissions and the combined endpoint (all-cause readmission or death).[51] Despite having only one trial of home-visiting at 30 days, this intervention category also consistently reduced readmission rates over 3 and 6 months we considered high intensity home-visiting programs efficacious in reducing all-cause readmissions and the combined outcome all-cause readmission or death at 30 days (low SOE). Evidence was insufficient to determine whether the following intervention types reduced 30-day all-cause readmissions (1 trial each; none showed efficacy): structured telephone support (STS), telemonitoring, and cognitive training. We found no eligible trials of other types of interventions that reported 30-day all-cause readmission rates.

Table 20 summarizes our main findings and SOE for 3- and 6-month readmission rates and mortality for timepoints with at least low SOE to support a conclusion. We found the best evidence of efficacy for improving our primary outcomes for home-visiting programs, STS, and multidisciplinary (MDS)-HF clinic interventions. Specifically, we found moderate SOE that home-visiting programs reduced all-cause readmission rates (3 and 6 months), HF-specific readmission rates (3 months), and a composite of all-cause readmission or death (6 months); that STS interventions reduced HF-specific readmission rates (3 and 6 months) and mortality (6 months); and that MDS-HF clinic interventions reduced all-cause readmission rates and mortality (both over 6 months).

Table 20. Summary of findings and strength of evidence for transitional care interventions: Readmission rates and mortality

Intervention Category	Outcome	Timing, months	N Trials; N Subjects	Risk Difference (95% CI)[a]	Numbers Needed to Treat	Strength of Evidence
Home-visiting	All-cause readmission	1	2; 418	High intensity interventions: -0.20 (-0.29, -0.10)	5	Low[b]
Home-visiting	All-cause readmission	3	4; 798	-0.12 (-0.18, -0.05)	8	Moderate
Home-visiting	All-cause readmission	6	5; 1102	-0.10 (-0.16, -0.05)	10	Moderate
Home-visiting	HF-specific readmission	3	1; 282	-0.14 (-0.23, -0.04)	8	Moderate[c]
Home-visiting	Composite endpoint[d]	1	1; 239	Hazard ratio (SE): 0.869 (0.033) vs. 0.737 (0.041)	NA[e]	Low[f]
Home-visiting	Composite endpoint	3	1; 239	Hazard ratio (SE): 0.071 (0.045) vs. 0.558 (0.047)	NA	Low[g]
Home-visiting	Composite endpoint	6	4; 824	-0.10 (-0.18, -0.02)	10	Moderate
Home-visiting	Mortality	30 days	1; 239	0.00 (-0.03, 0.03)	NA	Low[g]
Home-visiting	Mortality	3	2; 482	-0.02 (-0.06, 0.03)	NA	Moderate
Home-visiting	Mortality	6	5; 972	-0.04 (-0.09, 0.01)	NA	Moderate
STS	All-cause readmission	2 to 3	5; 1,024	-0.04 (-0.10, 0.03)	NA	Moderate
STS	All-cause readmission	6	6; 1,768	-0.06 (-0.16, 0.03)	NA	Low
STS	HF-specific readmission	3	5; 1,605	-0.04 (-0.07, -0.00)	25	Moderate
STS	HF-specific readmission	6	4; 677	-0.10 (-0.17, -0.03)	10	Moderate
STS	Composite endpoint	6	2; 866	-0.14 (-0.41, 0.13)	NA	Low
STS	Mortality	2 to 3	3; 618	-0.04 (-0.08, 0.00)	NA	Moderate
STS	Mortality	6	8; 1,724	-0.04 (-0.07, -0.01)	25	Moderate
Telemonitoring	All-cause readmission	2 to 3	2; 252	-0.00 (-0.12, 0.12)	NA	Moderate
Telemonitoring	All-cause readmission	6	1; 182	0.11 (-0.02, 0.24)	NA	Moderate[h]
Telemonitoring	HF-specific readmission	6	1; 182	0.08 (-0.03, 0.18)	NA	Moderate[h]
Telemonitoring	Mortality	3	2; 284	0.00 (-0.10, 0.10)	NA	Low
Telemonitoring	Mortality	6	2; 462	0.01 (-0.22, 0.24)	NA	Low
MDS-HF clinic	All-cause readmission	6	2; 336	-0.15 (-0.26, -0.05)	7	Moderate
MDS-HF clinic	Composite endpoint	6	2; 306	-0.11 (-0.21, 0.00)	NA	Moderate
MDS-HF clinic	Mortality	6	3; 536	-0.07 (-0.12, -0.01)	13	Moderate
Primarily Educational	Composite endpoint	6	2; 423	-0.05 (-0.29, 0.20)	NA	Low
Primarily Educational	Mortality	6	2; 423	0.02 (-0.07, 0.10)	NA	Low

[a] Entries in this column are RDs from our meta-analyses or risk difference calculations unless otherwise specified. Negative risk differences favor interventions over controls.

[b] Two home-visiting programs reported all-cause readmission at 30 days; the intervention studied by Naylor and colleagues was of higher intensity and showed efficacy. The lower intensity intervention studied by Jaarsma et al. did not show efficacy at 30 days (low SOE; NNT= NA).

[c] Although only one trial reported total number of people readmitted per group, we considered the findings consistent because one other trial reported on the number of readmissions per group and found a similar effect: patients receiving home visits had fewer total HF readmissions than did patients receiving usual care (measured as readmissions per patient year alive, relative risk, 0.54; $p<0.001$; N=200).[49]

[d] All-cause readmission or death.

[e] NA entry for numbers needed to treat (NNT) indicates that the risk difference (95% CI) was not statistically significant, so we did not calculate a NNT. NA for hazard ratios indicates that we could not calculate a NNT with the data provided by the investigators.

[f] Although only a single trial reported the number of people alive and not readmitted at 30 days and 3 months, we considered the consistency of similar programs reducing 3-month readmissions rates when grading the SOE for this intervention at 30 days.

[g] Although evidence was limited to one trial, consistency for the 30-day outcome was unknown, and evidence was imprecise, we upgraded the SOE because this intervention category has demonstrated no effect on mortality at 3 or 6 months—thus, increasing our confidence in the results of this single trial.[h] Although only a single trial reported on the number of people readmitted, we considered this finding consistent given that four other telemonitoring studies reported the total number of readmissions per group (rather than the number of people readmitted); all-cause readmissions did not differ between patients receiving telemonitoring and those receiving usual care at 30 days,[67] 3 months,[77] or 6 months.[67,73,75]

Abbreviations: CI = confidence level; MDS-HF, multidisciplinary heart failure clinic; N = number; NA = not applicable; NNT = number needed to treat; RD = risk difference; SE = standard error; SOE = strength of evidence; STS = structured telephone support.

For these outcomes, we calculated numbers needed to treat (NNTs) when data permitted (Table 20). The NNTs ranged from 5 to 10 for home-visiting programs, from 10 to 25 for STS interventions, and from 7 to 13 for MDS-HF clinic interventions. An NNT of 10 means, for example, that 10 people with HF would need to receive a home-visiting program following discharge (rather than usual care) to prevent one additional person from being readmitted over 3 months.

Our meta-analyses did not find telemonitoring or primarily educational interventions to be efficacious for any primary outcomes. In addition, our meta-analyses did not find home-visiting programs efficacious for reducing mortality at 30 days (low SOE), 3 or 6 months (moderate SOE); STS interventions were not efficacious for reducing all-cause readmissions at 3 months (moderate SOE) or 6 months (low SOE). We found insufficient evidence to support the efficacy of the following interventions in reducing readmission rates or mortality: most primarily educational interventions, nurse-led HF clinic interventions, primary care clinic interventions, peer support interventions, and cognitive training interventions (for people with HF and coexisting mild cognitive impairment).

Some experts have cautioned that inappropriate focus on reduction of readmission rates could negatively impact patient care and perhaps mortality. However, we found no evidence of such an effect—i.e., no interventions that reduced readmission rates but increased mortality.

Other Utilization Outcomes

Few included trials reported on emergency room (ER) visits or hospital days of subsequent readmissions; when these outcomes were reported, few trials reported measures in the same manner or at similar timepoints. No included trials reported the number of acute outpatient (non-ER) visits.

For ER visits, evidence was generally insufficient to determine whether transitional care interventions increased or decreased such visits. The one exception was STS; these interventions had no effect on the rate of ER visits over 6 months (low SOE).

For hospital days of subsequent readmissions, both home-visiting programs and STS reduced the total number of all-cause hospital days over 3 and 6 months (low SOE for both interventions). Otherwise, evidence was generally insufficient to determine whether other transitional care interventions increased or decreased hospital days of subsequent readmissions.

Quality of Life

Few trials measured quality of life or function using the same measures at similar timepoints. We found improvement in HF-specific quality of life, as measured by the Minnesota Living With Health Failure (MLWHF) questionnaire, was greater for home-visiting programs than usual care over 3 months (low SOE). Intervention and control groups did not differ on quality of life (MLWHFQ) for patients receiving home visits or primarily educational interventions at 6 months and for patients receiving STS over 3 and 6 months (both low SOE). Evidence was insufficient to determine whether other transitional care interventions improved quality of life.

Components of Effective Interventions

The two categories of interventions that reduced all-cause readmissions and the composite outcome—namely, home-visiting programs and MDS-HF clinic interventions—are multicomponent, complex interventions. We found no single-component intervention that reduced all-cause readmissions. As a whole, these two categories of interventions shared the following components:

- HF education emphasizing self-care, recognition of symptoms, and weight monitoring.
- HF pharmacotherapy emphasizing patient education about medications, promotion of adherence to medication regimens, and promotion of evidence-based HF pharmacotherapy before discharge or during followup (or both).
- Face-to-face contact following discharge via home-visiting personnel, MDS-HF clinic personnel (or both). In most cases, this contact occurred within 7 days of discharge.
- Streamlined mechanisms to contact care delivery personal (clinic personnel or visiting nurses or pharmacists) outside of scheduled visits (e.g., patient hotline).
- Mechanisms for postdischarge medication adjustment. In most cases, home-visiting personnel either directly recommended medication adjustment or assisted with coordination of care (e.g., with primary care provider or cardiologist) to facilitate timely medication adjustment based on a patient's needs (rather than advising patients to call for help themselves).

Two categories of interventions reduced mortality rates: STS (over 6 months), and MDS-HF clinic interventions (over 6 months). Both STS and MDS clinic interventions are multicomponent. As a whole, these two categories of interventions shared the following components:

- HF education emphasizing self-care, recognition of symptoms, and weight monitoring.
- A series of scheduled, structured visits (via telephone or clinic followup) that focused on reinforcing education and monitoring for HF symptoms.
- A mechanism to contact providers easily outside of scheduled visits (e.g., patient hotline).

Separating out individual components from the overall categories (or "bundles") of interventions that showed efficacy was not possible.

Intensity, Delivery Personnel, and Mode of Delivery

In general, intervention categories that included higher-intensity interventions (i.e., home-visiting programs, STS, MDS-HF clinic interventions) reduced all-cause readmissions or mortality, whereas categories with lower-intensity interventions (i.e., primarily educational interventions, nurse-led HF clinic interventions) did not. Within categories, evidence was generally insufficient to draw definitive conclusions about whether higher- or lower-intensity interventions are more or less efficacious in reducing all-cause readmissions or mortality. The one exception was home-visiting programs; higher intensity programs were effective in reducing all-cause readmission at 30 days while lower intensity programs were not effective. Subgroup analyses found no significant difference in efficacy based on intensity for STS programs. Subgroup analyses were not possible for other categories of interventions either because of lack of variation or too few trials reporting outcomes at similar timepoints.

The two categories of interventions that reduced all-cause readmissions and mortality (home-visiting programs and MDS-HF clinic interventions) were more likely to include teams of providers delivering the intervention (e.g., home visits that a nurse and pharmacist conducted together) than interventions that did not show efficacy (e.g., telemonitoring, primarily educational interventions). STS interventions (delivered primarily by nurses and pharmacists), were efficacious in reducing mortality but did not reduce all-cause readmissions. Within categories, evidence was insufficient to draw definitive conclusions about whether specific delivery personnel are more or less efficacious for reducing all-cause readmissions or mortality.

Across intervention categories, interventions were primarily delivered face-to-face or via technology (telephone, telemonitoring, video visits). The two categories of interventions delivered primarily face-to-face reduced all-cause readmission—i.e., home-visiting programs and MDS-HF clinic interventions. For these two categories, method of delivery did not vary within each category. STS reduced mortality; some of these interventions include a face-to-face component (e.g., predischarge educational intervention). In general, interventions primarily delivered remotely (i.e., telemonitoring, STS) did not reduce all-cause readmissions. Only STS interventions varied in the method of communication; our subgroup analyses for reduction in all-cause readmissions and mortality found no statistically significant difference by method of communication at any outcome timepoint.

Findings in Relation to What Is Already Known

The 2009 update of the 2005 American Heart Association/American College of Cardiology (AHA/ACC) guidelines addressed postdischarge HF interventions.[97] These guidelines focused on the importance of discharge planning, emphasizing written discharge instructions or educational material targeted to the patient or caregiver at discharge. The AHA/ACC guidelines also recommend that "postdischarge systems of care, if available, should be used to facilitate the transition to effective outpatient care for patients hospitalized with heart failure."

The 2010 Heart Failure Society of America guidelines are similar; their guidance emphasizes specific components of discharge planning.[98] No specific guidance is given on optimal transitional care interventions aimed at preventing early readmissions for patients with HF.

The results of this review make clear that certain intervention categories (or combinations of components) have better efficacy than others. Interventions such as home-visiting programs and MDS-HF clinic interventions reduced all-cause readmissions over 3 to 6 months, whereas telemonitoring interventions, as a category, did not. In general, intervention categories that

included higher-intensity interventions, with education on self-care delivered face-to-face over repeated visits through the transition from hospital to home (i.e., home-visiting programs, STS, MDS-HF clinic interventions) reduced all-cause readmissions or mortality, whereas categories with lower-intensity intervention (i.e., primarily educational interventions, nurse-led HF clinic interventions) did not. Guidelines that focus on written discharge instructions and early outpatient followup may not provide sufficient guidance on optimal strategies to reduce readmission and mortality.

Recent systematic reviews on transitional care or disease management interventions differed in scope from our review. One recent review of interventions to reduce 30-day readmissions excluded interventions that were disease specific; the authors found that most studies tested multicomponent discharge bundles. Common components of these interventions included postdischarge telephone calls and patient-centered discharge instructions—e.g., facilitation of patient engagement in the transition of care individually tailored for the patient's health and social circumstances.[31]

Previous reviews that focused specifically on HF interventions differed somewhat in conclusions based on the variation in classifying interventions and also in the scope (specifically timing for measuring outcomes) of this review. A 2011 review focused on STS and telemonitoring found that both intervention types reduced mortality at longer timepoints (6 to 12 months); however, the authors did not include more recent trials of telemonitoring.[30] A 2012 review that excluded timepoints before 6 months (opposite of our scope) focused on clinical service organization for HF. It classified interventions in three ways: (1) as case management (grouping home-visiting kinds of interventions with those involving telephone support), (2) clinical interventions (grouping all types of HF clinic interventions together [i.e., nurse-led and MDS clinic interventions]), and (3) multidisciplinary disease management interventions. The investigators found good evidence that case management interventions led by an HF specialist nurse reduced HF-related readmissions after 12 months and also reduced all-cause mortality.[29]

Applicability

Most studies included adults with moderate to severe HF. The mean age of subjects was generally in the 70s; very few studies enrolled patients who were, on average, either younger or older. We did not find evidence to confirm or refute whether treatments are more or less efficacious for many other subgroups, including groups defined by sex, racial or ethnic minorities, people with higher severity of HF, type of HF (e.g., diastolic vs. systolic) and those with certain coexisting conditions. Included trials commonly excluded patients who had end-stage renal disease or severe or unstable cardiovascular disease (e.g., recent myocardial infarction). The interventions included are applicable only to patients who are discharged to home; whether interventions would benefit patients who are discharged to another institution (e.g., assisted living facility) remains unclear.

One of three trials assessing MDS-HF clinic was conducted in the United States; the other two were conducted in Taiwan and Canada. Whether results reflect differences in populations or health care systems is unclear. Approximately one-half of the home-visiting programs were conducted in the United States; the others were conducted in Australia, the United Kingdom, and various European countries. Across most included trials, the majority of patients were prescribed an angiotensin-converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB) (when information was reported); however, the percentages of patients across trials who were prescribed beta-blockers at discharge varied widely across trials.

Whether "usual care" in trials published during the early 1990s is comparable to current practice is not clear. In general, studies did not report on details of usual care, including whether followup was scheduled soon after discharge or whether patients were receiving additional services such as home health care. Included trials were conducted in a mix of settings; these include academic medical centers, Department of Veterans Affairs hospital settings, and community hospitals.

Implications for Clinical and Policy Decisionmaking

Few trials reported readmission rates within 30 days following a HF hospitalization. Whether certain interventions that reduce readmissions at 3 and 6 months would also be effective in reducing earlier readmissions remains uncertain. Data based on Medicare claims suggest that 35.2 percent of 30-day readmissions are for HF; the remainder are for diverse indications (e.g., renal disorders, pneumonia, arrhythmias, and septicemia or shock).[6] We found the best evidence for interventions that provided relatively frequent in-person monitoring following discharge—specifically, home-visiting programs and MDS-HF clinic interventions. The one trial which showed efficacy for reducing 30-day all-cause readmission provided frequent, in-home monitoring that began within 24 hours of discharge.[51] Interventions that did not show efficacy for all-cause readmissions tended to focus more narrowly on HF self-management alone (e.g., STS, primarily educational interventions). For reducing all-cause readmission, focusing on HF self-care training or weight monitoring alone does not appear sufficient.

Current clinical practice in the care of adults with HF after hospitalization varies greatly. A recent telephone survey of 100 U.S. hospitals found wide variation in education, discharge processes, care transition, and quality-improvement methods for patients hospitalized with HF.[18] As mentioned in the introduction to this review, readmission rates vary by both geographic location and insurance coverage.[7] Our findings provide some guidance to quality-improvement efforts, which aim to reduce readmissions for people with HF. Specifically, systems or providers aiming to implement interventions to improve transitional care for patients with HF may be uncertain about what type of intervention to implement. Our results suggest that home-visiting programs, and MDS-HF clinic interventions currently have the best evidence for reducing all-cause readmissions and should receive the greatest consideration. Although we did not find direct evidence on whether certain types of interventions increase or decrease caregiver or self-care burden, clinicians should consider the effect of transitional care interventions on caregivers (e.g. burden of transportation) when recommending an intervention, with the goal of minimizing additional burden.

Limitations of the Comparative Effectiveness Review Process

The scope of this review targeted adults hospitalized for HF. We did not evaluate transitional care interventions either for adults hospitalized for other reasons or for children and adolescents.

The interventions in the included trials were heterogeneous and could probably be categorized using a variety of approaches. We classified them in a manner that we believe is both descriptive and informative, but other approaches to categorization could lead analysts to different conclusions. Other reviews have highlighted the difficulty in classifying studies into distinct categories. For example, one trial by Rainville et al.[69] classified as STS in our report and

also classified as STS in a 2011 Cochrane review[30] while a 2012 Cochrane review classified the same study as case management, grouping it with trials that assessed a home-visiting program.[29]

We use the term "transitional care" broadly; generally we were guided by Coleman's definition as "a set of actions designed to ensure the coordination and continuity of health care as patients transfer between different locations or different levels of care within the same location" (p. 30).[24] The included interventions are diverse in terms of whether they aimed to coordinate care at the provider level or focused more on strategies to transfer care back to the patient (e.g., through self-care training for HF management). We did not include or exclude studies based on any specific set of components; for that reason, included trials assess diverse interventions. We chose to cast a broad net include a comprehensive set of strategies to reduce readmissions that would be useful to stakeholders in different settings (hospitals, outpatient clinics, or others).

Our inclusion and exclusion criteria specified that included studies had to enroll patients during (or within 1 week) of a hospitalization for HF and also had to measure a readmission rate before 6 months. We did not include readmission rates or mortality rates measured longer than 6 months; interventions that we did not find efficacious may still be beneficial in long-term disease management in patients with HF (e.g., perhaps for reducing 12-month readmission rates).

Finally, publication bias and selective reporting are potential limitations. Although we searched for unpublished studies and unpublished outcomes, we did not find direct evidence of either of these biases. Many of the included trials were published before trial registries (e.g., clinicaltrials.gov) became available; had we been able to consult such registries, we would have had greater certainty about the potential for either type of bias.

Limitations of the Evidence Base

The evidence base was inadequate to draw conclusions for some of our questions or subquestions of interest. In particular, as described above, direct evidence was insufficient to permit us to draw any conclusions on comparative effectiveness of transitional care interventions. In addition, evidence was quite limited for some outcomes (e.g., readmissions within 30 days, utilization outcomes, and quality of life). Evidence was similarly insufficient to draw any definitive conclusions about whether any transitional care interventions are more or less efficacious in reducing readmissions or mortality based on patient subgroups defined by age, sex, race, ethnicity, socioeconomic status, disease severity, or coexisting conditions. We found just two eligible trials reporting information on different subgroups. We identified little evidence on the potential harms of transitional care interventions, such as whether they increase caregiver burden or increase the rate of ER visits. None of the included trials measured caregiver burden, which is relevant given that health care interventions affect not only the health of the individual receiving the intervention but also the health of those close to the patient.

Many of the included trials had methodological limitations introducing some risk of bias. Some trials did not clearly describe methods used for assessing utilization outcomes (e.g., readmissions, ER visits). Methods of handling missing data varied; some trials did nothing to address missing data (i.e., analyzed only completers). However, many trials conducted true intention-to-treat analyses and used appropriate methods of handling missing data, such as imputing return readmissions for subjects lost to followup.

Limitations also included inadequate sample size and significant heterogeneity of outcome measures across trials (specifically types of readmission rates). Reporting of use of health services other than for the primary outcomes, such as ER visits, was variable across the included studies.

Sometimes usual care and certain aspects of treatment interventions were not adequately described. Specifically, descriptions of whether (and how) interventions addressed medication management were often unsatisfactory. Categories of interventions that showed efficacy (e.g., MDS-HF clinic interventions and home-visiting programs) often included frequent visits with clinicians. Separating out individual components that are necessary from the overall type of interventions that showed efficacy was not possible. Moreover, some confounding components that were not described may be associated with efficacy as well (e.g., addressing social needs, optimizing HF pharmacotherapy).

Research Gaps

We identified important gaps in the evidence that future research could address; many are highlighted above. Of note, these gaps relate only to the key questions addressed by this report, and they should not eliminate a wide range of potentially important research that falls outside the specified scope of this review. Table 21 summarizes the gaps and offers examples of potential future research that could address the gaps.

Also, we identified several methodological issues that increased the risk of bias for trials measuring readmission rates which could be addressed in future research. Often trials provided inadequate description of the method of ascertaining health care utilization outcomes (e.g., readmissions, ER visits)–specifically whether measurements were based on patient report, chart review or some combination of measurements. There were concerns about masking of outcome assessments; for example, in some trials personnel delivering the intervention also appeared to be primarily responsible for measuring health care utilization. Future studies should consider methods (such as blinded outcome assessments) that guard against measurement bias.

Table 21. Evidence gaps for future research, by key question

KQ	Evidence Gap	Potential Future Research
1	Few trials measured 30-day all-cause readmission outcomes (including those rated as high or unclear risk of bias); we found low SOE for home-visiting programs in reducing all-cause readmission and the combined outcome (all-cause readmission or death). Evidence was insufficient to determine the efficacy of other intervention categories in reducing 30-day readmission rates.	Future studies should evaluate whether interventions that show efficacy in reducing 3- and 6-month readmission rates are also effective in reducing 30-day readmission rates (e.g., care in a MDS- HF clinic following discharge). Future trials should ensure that the sample size and method of ascertaining readmission outcomes are adequate to determine the effect of transitional care interventions on 30-day readmission rates.
1, 3-4	Descriptions of key intervention components (content and process) were inconsistently reported across included studies. Some trials provided great detail, others very little. There does not appear to be a common conceptual framework used among researchers who aim to assess whether interventions reduce readmissions for the included timepoints (30 days to 6 months).	Future research of transitional care interventions could rely on guidance from the AHA statement addressing taxonomy for disease management [1] that provides guidance used to categorize and compare disease management programs. Alternatively, this taxonomy could be amended to include more specific guidance on categorizing transitional care type interventions (e.g., incorporate subdomains in the "environment" domain that is more specific to the transition period).
1	Evidence was insufficient to determine the comparative effectiveness of transitional care interventions.	Future RCTs should address whether certain types of interventions are more efficacious than others. For example: (1) home-visiting programs that are higher vs. lower intensity or that differ in specific components (2) MDS- HF clinic followup compared with home visits that provide similar periodicity of followup and content (e.g., education on self-care and medication reconciliation).

Table 21. Evidence gaps for future research, by key question (continued)

KQ	Evidence Gap	Potential Future Research
1	Telemonitoring interventions did not reduce readmissions over 6 months; whether this can be attributed to lack of care coordination or other factors remains unclear.	Future RCTs of telemonitoring interventions should include factors that appear to be necessary (or add benefit). For example, telemonitoring that starts immediately after discharge, is combined with initial in-person visits (in the clinic or in the home), and is integrated with the patient's established outpatient care
1,2	Evidence was insufficient to determine whether interventions based in a primary care clinic can reduce readmissions for patients with HF (the one included primary care intervention occurred in a Veterans Administration hospital setting).	Future studies should focus on whether interventions delivered in a primary care setting, featuring components shown to be efficacious (e.g., in-person self-management education and monitoring during home visits or frequent clinic appointments) reduce 30-day readmission rates. These interventions may be more applicable (compared to interventions delivered in a more specialized setting).
2	Evidence was insufficient to determine efficacy of transitional care interventions in reducing 30-day mortality.	Future trials and observational studies should evaluate whether interventions that reduce 30-day readmission rates increase or decrease mortality. Interventions that show efficacy in RCTs may not perform differently under diverse settings. There remains a concern about the relationship between reductions in 30-day readmission rates and mortality, especially for vulnerable populations.
2	Literature does not address the effect of interventions on burdens placed on either patients themselves or their caregivers.	Future research should include validated caregiver burden measures as well as patient-reported measures that address self-care burden and quality of life. Beyond changes in disease specific outcomes (MLWHFQ), evidence was generally insufficient to determine the effect of interventions on patient reported outcomes.
5	Evidence was insufficient to determine whether certain subgroups of patients benefit from transitional care interventions.	Future research could assess whether readmission rates differ by disease severity, low-income patients, or patients from racial and ethnic minorities.

Abbreviations: AHA = American Heart Association; KQ = key question; MDS-HF, multidisciplinary heart failure clinic; MLWHFQ = Minnesota Living With Heart Failure Questionnaire; RCT = randomized controlled trial.

Conclusions

Few trials evaluating transitional care interventions for adults with HF reported 30-day readmission rates; we identified one high intensity home-visiting trial that reduce all-cause readmission and the combined endpoint all-cause readmission or death (low SOE). We found the best evidence of efficacy for improving at least one of our primary outcomes over 3 to 6 months for three main approaches: home-visiting programs, STS, and MDS-HF clinic interventions. Specifically, we found that home-visiting programs reduced all-cause readmission rates (30 days, 3 and 6 months), HF-specific readmission rates (3 months), and a composite of all-cause readmission or death (30 days, 3 and 6 months); that STS interventions reduced HF-specific readmission rates (3 and 6 months) and mortality (6 months); and that MDS-HF clinic interventions reduced all-cause readmission rates and mortality (both over 6 months). The SOE for these conclusions was moderate. For these outcomes, NNTs ranged from 5 to 10 for home-visiting programs, from 10 to 25 for STS interventions, and from 7 to 13 for MDS-HF clinic interventions. Current evidence does not establish the efficacy of telemonitoring interventions or primarily educational interventions for reducing readmissions or mortality. Direct evidence was insufficient to conclude whether one type of intervention was more efficacious than any other type. Evidence was generally insufficient to determine whether the efficacy of interventions differed for subgroups of patients.

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Abbreviations and Acronyms

Abbreviation or Acronym	Definition
ACEI	Angiotensin-converting enzyme inhibitor
AF	Atrial fibrillation
AHA/ACC	American Heart Association/American College of Cardiology
AHRQ	Agency for Healthcare Research and Quality
AMA	American Medical Association
ARB	Angiotensin II receptor blocker
BB	Beta-blocker
CAD	Coronary artery disease
CD-ROM	Compact Disk Read-Only Memory
CI	Confidence interval
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CMS	Centers for Medicare and Medicaid Services
COPD	Chronic obstructive pulmonary disease
DM	Diabetes mellitus
EF	Ejection fraction
EPC	Evidence-based Practice Center
ER	Emergency room
EuroQoL or EQ-5D	European Quality of Life – 5 Dimensions
HF	Heart failure
HR	Hazard ratio
HV	Home visiting
IHD	Ischemic heart disease
ITT	Intention-to-treat
KQ	Key Question
LVEF	Left ventricular ejection fraction
MCI	Mild cognitive impairment
MDS	Multidisciplinary
MDS-HF	Multidisciplinary heart failure clinic
Med	Medium
MI	Myocardial infarction
MLWHFQ	Minnesota Living With Heart Failure Questionnaire
N	Number (group or sample size)
NA	Not applicable
NNT	Number needed to treat
NR	Not reported
NS	Not significant
NYHA	New York Heart Association functional classification
PICOTS	Populations, Interventions, Comparators, Outcomes, Timing, Settings
PRISMA	Preferred Reporting Items in Systematic Reviews and Meta-Analyses
ProBNP	Probrain natriuretic peptide
QOL	Quality of life
RCT	Randomized controlled trial
RD	Risk difference
RR	Relative risk
ROB	Risk of bias
SD	Standard deviation
SE	Standard error
SF-12	Medical Outcomes Study Short Form (12 items)
SF-36	Medical Outcomes Study Short Form (36 items)
SMD	Standardized mean difference
SOE	Strength of evidence
STS	Structured telephone support

TEP	Technical Expert Panel
TM	Telemonitoring
UC	Usual care
UK	United Kingdom
Unc	Unclear
U.S.	United States
VA	Veterans Affairs
VAMC	Veterans Affairs Medical Center
WMD	Weighted mean difference
6MWT	6 Minute Walk Test

Glossary of Terms

Term or Scale	Definition
Heart failure (HF)	A chronic, progressive condition in which the heart muscle cannot pump sufficient blood to oxygenate the body's need for blood and oxygen. The most common hospital discharge diagnosis among the elderly in the U.S.[1]
Quality of life (QOL)	A multidimensional, broad-ranging concept that can be defined as an individual's perception of their position in life in the context of the culture and value systems in which they live. Factors such as physical health, mental health, and social relationships can affect a person's QOL.[2]
Minnesota Living With Heart Failure Questionnaire (MLWHFQ)	QOL measure for individuals with HF with a range of scores from 0-105, with decreasing scores indicating improvement.
6-Minute Walk Test	Measure of functional status that tests functional exercise capacity in a variety of populations. This is the distance a person can walk within 6 minutes on a flat surface, with a range of 0-400+ meters. Increasing distances indicate improvement, and an improvement of 54 meters is considered clinically significant.[3]
New York Heart Association (NYHA) Classification	Classification system for heart failure disease severity; patients are classified in one of four categories based on the following: how much they are limited during physical activity; the limitations/symptoms in regards to normal breathing and varying degrees in shortness of breath and or angina pain. Range of scores from II-IV, with decreasing scores indicating improvement.
Medical Outcomes Study Short Form Health Survey with 36 items (SF-36)	QOL measure with a range of scores from 0-100, with increasing scores indicating improvement.
Medical Outcomes Study Short Form with 12 items (SF-12)	Shorter version of the SF-36 instrument. Also uses a range of scores from 0-100, with increasing scores indicating improvement.
European Quality of Life- 5 Dimensions (EuroQoL or EQ-5D)	QOL measure with a range of scores from 0-100, with increasing scores indicating improvement.
Risk difference (RD)	An absolute measure of how an intervention or exposure changes the risk or incidence of a dichotomous outcome, or an outcome with two potential values. Calculated as the difference in the incidence or risk of an event in an intervention or exposure group from the incidence or risk of the same event in a control or other intervention group.
Risk ratio (RR)	The ratio of the incidence of a given outcome in an intervention or exposure group compared with the incidence of that same outcome in a control or other intervention group.
Standardized mean difference (SMD)	Used in a meta-analysis when all of the analyzed studies evaluate the same continuous outcome but with different scales. Calculated as the ratio of the difference in mean outcome between groups to the standard deviation of the outcome among patients.[4]
Weighted mean difference (WMD)	Mean difference calculated for continuous data from studies in a meta-analysis in which the results of some studies make a greater contribution to the total than others.[5]

Glossary References

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Appendix A. Literature Search Strategies

Published Literature

PubMed. 1295 records retrieved.

Search String	Search Terms	Number of Results
#1	Search (“congestive heart failure” OR “heart failure, congestive” OR “heart failure”[mesh])	95131
#2	Search (Readmission OR rehospitalization OR recurrence[mesh] OR “patient readmission”[mesh])	161929
#3	Search ("case management”[mesh] OR “rehabilitation”[mesh] OR “continuity of patient care”[mesh] OR “patient discharge”[mesh] OR “patient transfer”[mesh] OR transition* OR postdischarge OR post-discharge OR coordination OR coordinate OR transfer OR post-acute care OR postacute care OR post-hospital* OR posthospital* OR subacute care OR sub-acute care OR discharge OR referral OR continuity OR "critical pathways"[MeSH Terms] OR “critical pathways”[Text Word] OR “critical pathway”[All Fields] OR “critical path”[all fields] OR “critical paths”[all fields] OR “clinical path” [all fields] OR “clinical paths” [all fields] OR “clinical pathway” [all fields] OR “clinical pathways”[all fields] OR "telemedicine"[MeSH Terms] OR telemedicine[Text Word] OR telehealth[all fields] OR eHealth[all fields] OR “Mobile Health”[all fields] OR “Home Care Services, Hospital-Based”[MeSH] OR “Hospital Based Home Cares”[All Fields] OR “Hospital Home Care Services”[All Fields] OR “Hospital-Based Home Care”[All Fields] OR “Hospital Based Home Care”[All Fields] OR “Hospital-Based Home Cares”[All Fields] OR “home nursing”[MeSh] OR “Nonprofessional Home Care”[All Fields] OR “home nursing”[all fields] OR “Non-Professional Home Care”[All Fields] OR “Physical Therapy Modalities”[MeSH] OR “physical therapy”[All Fields] OR “physical therapies”[all fields] OR “Exercise Therapy”[MeSH] OR “exercise therapy”[All Fields])	1132712
#4	Search (((randomized[title/abstract] AND controlled[title/abstract] AND trial[title/abstract]) OR (controlled[title/abstract] AND trial[title/abstract]) OR "controlled clinical trial"[publication type] OR "Randomized Controlled Trial"[Publication Type] OR "Single-Blind Method"[MeSH] OR "Double-Blind Method"[MeSH] OR "Random Allocation"[MeSH]))	533347
#5	Search ("review"[Publication Type] AND "systematic"[tiab]) OR "systematic review"[All Fields] OR ("review literature as topic"[MeSH AND "systematic"[tiab]) OR "meta-analysis"[Publication Type] OR "meta-analysis as topic"[MeSH Terms] OR "meta-analysis"[All Fields]	106432
#6	Search (“prospective cohort” OR “prospective studies”[MeSH] OR (prospective*[All Fields] AND cohort[All Fields] AND (study[All Fields] OR studies[All Fields])) OR (controlled[title/abstract] AND trial[title/abstract]) OR "controlled clinical trial"[publication type])	520244
#7	Search (#1 AND (#2 OR #3) AND (#5 OR #4))	1116
#8	Search (#1 AND (#2 OR #3) AND #6)	1123
#9	Search ((Autobiography[Publication Type] OR Bibliography[Publication Type] OR Biography[Publication Type] OR Case Reports[Publication Type] OR Classical Article[Publication Type] OR comment[Publication Type] OR Congresses[Publication Type] OR Consensus Development Conference[Publication Type] OR Dictionary[Publication Type] OR Directory[Publication Type] OR Editorial[Publication Type] OR Electronic supplementary materials[Publication Type] OR Festschrift[Publication Type] OR In Vitro[Publication Type] OR Interactive Tutorial[Publication Type] OR Interview[Publication Type] OR Lectures[Publication Type] OR Legal Cases[Publication Type] OR Legislation[Publication Type] OR Letter[Publication Type] OR News[Publication Type] OR Newspaper article[Publication Type] OR Patient Education Handout[Publication Type] OR Personal Narratives[Publication Type] OR Periodical Index[Publication Type] OR Pictorial works[Publication Type] OR Popular works[Publication Type] OR Portraits[Publication Type] OR Scientific Integrity Review[Publication Type] OR Video Audio Media[Publication Type] OR Webcasts[Publication Type]))	3486741
#10	Search (#7 NOT #9)	1094
#11	Search (#7 NOT #9) Filters: Humans	1075
#12	Search(#7 NOT #9) Filters: Humans; English	1009

Search String	Search Terms	Number of Results
#13	Search (#7 NOT #9) Filters: Publication date from 2007/07/01; Humans; English	511
#14	Search (#8 NOT #9)	1109
#15	Search (#8 NOT #9) Filters: Humans	1100
#16	Search (#8 NOT #9) Filters: Humans; English	1044
#17	Search (#8 NOT #9) Filters: Publication date from 1990/01/01; Humans; English	1017
#18	Search (#13 OR #17)	1295

Cochrane Library: 1174 records retrieved.

Search String	Search Terms	Number of Results
#1	"congestive heart failure" or "heart failure, congestive"	3574
#2	MeSH descriptor: [Heart Failure] explode all trees	4968
#3	#1 or #2	7003
#4	MeSH descriptor: [Recurrence] explode all trees	11228
#5	MeSH descriptor: [Patient Readmission] explode all trees	651
#6	readmission or rehospitalization	2540
#7	#4 or #5 or #6	13619
#8	MeSH descriptor: [Case Management] explode all trees	569
#9	MeSH descriptor: [Rehabilitation] explode all trees	12409
#10	MeSH descriptor: [Continuity of Patient Care] explode all trees	448
#11	MeSH descriptor: [Patient Discharge] explode all trees	910
#12	MeSH descriptor: [Patient Transfer] explode all trees	103
#13	MeSH descriptor: [Critical Pathways] explode all trees	223
#14	MeSH descriptor: [Telemedicine] explode all trees	961
#15	MeSH descriptor: [Home Care Services, Hospital-Based] explode all trees	227
#16	MeSH descriptor: [Home Nursing] explode all trees	297
#17	MeSH descriptor: [Physical Therapy Modalities] explode all trees	12939
#18	MeSH descriptor: [Exercise Therapy] explode all trees	5562
#19	transition* or postdischarge or "post-discharge" or coordination or coordinate or transfer or "post-acute care" or "postacute care" or post-hospital* or posthospital* or "subacute care" or "sub-acute care" or discharge or referral or continuity or "critical pathways" or "critical pathway" or "critical path" or "critical paths" or "clinical path" or "clinical paths" or "clinical pathway" or "clinical pathways" or telemedicine or telehealth or eHealth or "Mobile Health" or "Hospital Based Home Cares" or "Hospital Home Care Services" or "Hospital-Based Home Care" or "Hospital Based Home Care" or "Hospital-Based Home Cares" or "Nonprofessional Home Care" or "home nursing" or "Non-Professional Home Care" or "physical therapy" or "physical therapies" or "exercise therapy"	42217
#20	#8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19	53644
#21	#3 and (#7 or #20)	1431
#22	#3 and (#7 or #20) in Trials	889
#23	#3 and (#7 or #20) from 1990, in Trials	866
#24	#3 and (#7 or #20) in Cochrane Reviews (Reviews and Protocols) and Other Reviews	375
#25	#3 and (#7 or #20) from 2007, in Cochrane Reviews (Reviews and Protocols) and Other Reviews	308
#26	#23 or #25	1174

CINAHL: 283 records retrieved

Search String	Search Terms	Number of Results
S1	(MH "Heart Failure")	16,241
S2	((MH "Recurrence") OR (MH "Readmission"))	19,303
S3	((MH "Case Management") OR (MH "Rehabilitation") OR (MH "Continuity of Patient Care") OR (MH "Patient Discharge") OR (MH "Transfer, Discharge") OR (MH "Critical Path") OR (MH "Telemedicine") OR (MH "Telehealth") OR (MH "Home Health Care") OR (MH "Home Rehabilitation") OR (MH "Home Nursing") OR (MH "Physical Therapy") OR (MH "Therapeutic Exercise"))	82,649
S4	(MH "Randomized Controlled Trials") OR (MH "Nonrandomized Trials") OR (MH "Single-Blind Studies") OR (MH "Double-Blind Studies") OR (MH "Random Assignment")	56,419
S5	((MH "Meta Analysis") OR (MH "Systematic Review"))	23,286
S6	(MH "Prospective Studies") OR (MH "Clinical Trials")	210,981
S7	S1 AND (S2 OR S3) AND (S5 OR S4)	148
S8	S1 AND (S2 OR S3) AND S6	342
S9	Search (S7) Limiters - Human	116
S10	Search(S7) Limiters - Human; Language: English	115
S11	Search (S7) Limiters - Published Date from: 20070701-20130431; Human; Language: English	70
S12	Search (S8) Limiters - Human	257
S13	Search (S8) Limiters - Human; Language: English	254
S14	Search (S8) Limiters - Published Date from: 19900101-20130431; Human; Language: English	254
S15	S11 OR S14	302
S16	(MH "Autobiographies") OR (MH "Biographies") OR (MH "Bibliography and References") OR (MH "Bibliography, Descriptive") OR (MH "Case Studies") OR (MH "Congresses and Conferences") OR (MH "Reference Books") OR (MH "Edit and Review") OR (MH "In Vitro Studies") OR (MH "Interviews") OR (MH "Lecture") OR (MH "Legal Procedure") OR (MH "Legislation") OR (MH "News") OR (MH "Newspapers") OR (MH "Historical Records") OR (MH "Narratives") OR (MH "Life Histories") OR (MH "Videorecording") OR (MH "Audiovisuals") OR (MH "Audiorecording") OR (MH "World Wide Web Applications")	191483
S17	S15 NOT S16	283

Gray Literature

ClinicalTrials.gov: 455 records retrieved.

Search String	Search Terms	Number of Results
#1	Conditions: "congestive heart failure" OR "heart failure"	2109
#2	Interventions: Readmission OR rehospitalization OR recurrence OR patient readmission	954
#3	Interventions: case management OR rehabilitation OR discharge OR transition OR post-discharge OR coordination OR transfer OR post-acute care OR post-hospital OR subacute care OR referral OR continuity OR critical path OR clinical path OR telemedicine OR telehealth	11879
#4	Interventions: eHealth OR Mobile Health OR Hospital Based Home Care OR Nonprofessional Home Care OR home nursing OR physical therapy OR Exercise Therapy	7650
#5	#1 AND #2	25
#6	#1 AND #3	261
#7	#1 AND #4	235
#8	#5 OR #6 OR #7	455

WHO ICTRP: 70 records retrieved.

Search String	Search Terms	Number of Results
#1	Condition: heart failure	2162
#2	Intervention: Readmission OR rehospitalization OR recurrence OR “patient readmission”	306
#3	Intervention: “case management” OR “rehabilitation” OR “discharge” OR “transition” OR “post-discharge” OR “coordination” OR “transfer” OR “post-acute care” OR “post-hospital” OR “subacute care” OR “referral” OR “continuity” OR “critical path” OR “clinical path” OR “telemedicine” OR telehealth	88
#4	Interventions: eHealth OR “Mobile Health” OR “Hospital Based Home Care” OR “Nonprofessional Home Care” OR “home nursing” OR “physical therapy” OR “Exercise Therapy”	6167
#5	#1 AND #2	6
#6	#1 AND #3	6
#7	#1 AND #4	96
#8	#5 OR #6 OR #7	102
#9	(#5 OR #6 OR #7) NOT clinicaltrials.gov	70

Appendix B. List of Studies Excluded after Full-Text Level Review

Reasons for exclusion signify only the usefulness of the articles for this study and are not intended as criticisms of the articles.

Ineligible Publication Type (n = 41)

1. Authors not named. CHF education saved this hospital $173,000. RN. 1998 Nov;61(11):24C-F, H. PMID: 10205572.
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Appendix C. Characteristics of Interventions

Table C1. Intervention Components for Primarily Educational Interventions

Author, year	Risk of Bias	Intensity	Primary Mode of Delivery	Delivery Personnel	Self-management Education/ Promotion	Weight-monitoring Education or Promotion	Diet/Sodium Restriction Education or Promotion	Promotion of Medication Adherence	Exercise Education or Promotion	Other or Unspecified HF Education	Medication Reconciliation	Setting/ Timing of Education [a]	Planned Telephone Follow-up Post d/c	Timing of First Phone or TM Follow-up (Days)	Phone Follow-up Conducted by Same Personnel delivering inpatient Intervention Component	Patient Phone Hotline	Timing of First Clinic Visit Post d/c
Albert, 2007[1]	High	Low	Video	NA	x	x	x	x	x			Post-d/c					
Koelling, 2005[2]	Low	Low	Face-to-Face	Nurse	x	x	x	x		x		Pre-d/c					
Linne, 2006[3]	Unclear	Low	Interactive CD-ROM	NA	x	x		x	x			Both					
Nucifora, 2006[4]	Med	Med.	Face-to-Face	Nurse	x	x	x	x				Both	x	> 7 days	x	x	> 14 days

[a] Both = both pre- and post-d/c.

Abbreviations: CD-ROM = compact disk read-only memory; d/c = discharge; HF = heart failure; MDS = multidisciplinary; Med = Medium.

Table C2. Intervention Components for Home Visiting Interventions (Part 1)

Author, year	Risk of Bias	Intensity	Primary Mode of Delivery	Delivery Personnel	Self-management education/ promotion	Weight-monitoring education or promotion	Diet/Sodium restriction education or promotion	Promotion of Medication Adherence	Exercise Education or promotion	Other or unspecified HF education	Medication Reconciliation	Setting/ Timing of Education [a]
Aldamiz-Echevarría Iraúrgui, 2007[5]	Med	High	Face-to-Face	MDS	x	x	x	x		x	x	Post-d/c
Holland, 2007[6]	Med	Med	Face-to-Face	Pharm.	x	x	x	x	x	x	x	Post-d/c
Jaarsma, 1999[7]	Med	Med	Face-to-Face	Nurse	x		x	x		x		Both
Kimmelstiel, 2004[8]	Med	Med	Face-to-Face	Nurse	x	x	x	x		x		Post-d/c
Kwok, 2007[9]	Med	High	Face-to-Face	Nurse	x		x	x	x		x	Both
Naylor, 2004[10]	Low	High	Face-to-Face	Nurse	x	x	x	x			x	Both
Pugh, 2001[11]	High	Med	Face-to-Face	Nurse	x					x		Other
Rich, 1993[12]	Med	High	Face-to-Face	MDS	x	x	x	x		x	x	Both
Rich, 1995[13]	Med	High	Face-to-Face	MDS	x	x	x	x		x	x	Both
Sethares, 2004[14]	High	Med	Face-to-Face	Nurse	x	x	x	x				Both
Stewart, 1998[15]	Med	Med	Face-to-Face	Nurse	x			x				Both
Stewart, 1999[16]	Med	Med	Face-to-Face	Nurse	x	x		x	x			Post-d/c (based on assessment)
Thompson, 2005[17]	High	High	Face-to-Face	Nurse	x	x	x	x	x	x	x	Both
Triller, 2008[18]	Unclear	Med	Face-to-Face	Pharm.	x	x	x	x			x	Post-d/c

[a] Both = both pre- and post-d/c.

Abbreviations: d/c= discharge; HF = heart failure; MDS = multidisciplinary; Med = Medium; Pharm. = Pharmacist

Table C3. Intervention Components for Home Visiting Interventions (Part 2)

Author, year	Risk of Bias	Transition Coach or Coordination Between Inpatient/ Outpatient Providers	Individua-lized d/c Plan	Provider Conti-nuity	Planned Tele-phone Follow-up Post d/c	Timing of First Phone or TM Follow-up (Days)	Phone Follow-up Conducted by Same Personnel Delivering Inpatient Intervention Component	Series of Structured calls	Patient Phone Hotline	Timing of First Home Visit (Days)
Aldamiz-Echevarría Iraúrgui, 2007[5]	Med								x	1-2
Holland, 2007[6]	Med									< 14
Jaarsma, 1999[7]	Med		x		x	≤ 7	x		x	< 7
Kimmelstiel, 2004[8]	Med							x (as needed)	x	< 7
Kwok, 2007[9]	Med	x		x					x	< 7
Naylor, 2004[10]	Low	x	x						x	< 1
Pugh, 2001[11]	High		x		x			x		unclear
Rich, 1993[12]	Med	x	x		x (as needed)		x		x	1-2
Rich, 1995[13]	Med	x	x		x (as needed)		x		x	1-2
Sethares, 2004[14]	High	x								> 7
Stewart, 1998[15]	Med	x								< 7
Stewart, 1999[16]	Med									> 7
Thompson, 2005[17]	High	x							x	> 7
Triller, 2008[18]	Unclear									< 7

Abbreviations: d/c = discharge; HF = heart failure; hrs = hours; Med = Medium; TM = telemonitoring.

Table C3. Intervention Components for Home Visiting Interventions (Part 3)

Author, year	Risk of Bias	Number of Scheduled Home Visits	Medi-cation Reconci-liation During Home Visit	Unspecified HF Education/ Promotion During Home Visit	Symptom Checklist or Clinical Assessment During Home Visit *(e.g. History, Symptoms)*	Physical Exam During Home Visit	Home Visiting Personnel Coordinates Care or Collaborates With Outpatient Provider	Clinic Personnel On-Call/ Available for Acute Symptom Management *(Outside of Scheduled Appt)*	Medication Optimization; Pre-d/c or During Intervention
Aldamiz-Echevarría Iraúrgui, 2007[5]	Med	2 to 3	x	x	x	x			x
Holland, 2007[6]	Med	2	x	x	x		x		x
Jaarsma, 1999[7]	Med	1		x					
Kimmelstiel, 2004[8]	Med	1	x	x	x		x		
Kwok, 2007[9]	Med	6[a]	x		x	x	x		x
Naylor, 2004[10]	Low	8	x	x	x		x		
Pugh, 2001[11]	High	1[b]	x	x					
Rich, 1993[12]	Med	>3	x	x		x			x
Rich, 1995[13]	Med	>3	x	x		x			x
Sethares, 2004[14]	High	2 to 3	x						
Stewart, 1998[15]	Med	1	x	x			x		
Stewart, 1999[16]	Med	1		x	x	x	x		
Thompson, 2005[17]	High	1		x	x	x		x	x
Triller, 2008[18]	Unclear	other	x	x			x		x

[a] In Kwok et al., an average of 6 visits took place, including the initial inpatient visit, but more visits were scheduled for individual patients if needed.[9]

[b] Additional visits were scheduled at home or in a clinic based on individual need.[19]

Abbreviations: appt = appointment; d/c = discharge; HF = heart failure; Med = Medium.

Table C4. Intervention Components for Clinic-based Interventions (Part 1)

Author, year	Risk of Bias	Intensity	Primary Mode of Delivery	Delivery Personnel	Self-management education/ promotion	Weight-monitoring education or promotion	Diet/Sodium restriction education or promotion	Promotion of Medication Adherence	Other or unspecified HF education	Medication Reconciliation	Setting/ Timing of Education [a]	Transition coach or coordination between inpatient/ outpatient providers
Ekman, 1998[20]	Med	Med	Face-to-Face	Nurse		x		x			Post-d/c	
Stromberg, 2003[21]	Low	Med	Face-to-Face	Nurse	x	x	x	x			Post-d/c	
Ducharme, 2005[22]	Low	High	Face-to-Face	MDS	x	x	x	x	x	x	Post-d/c	
Kasper, 2002[23]	Low	High	Face-to-Face	MDS	x				x		Post-d/c	
Liu, 2012[24]	Low	High	Face-to-Face	MDS	x			x		x	Both	x
McDonald, 2001[25]; McDonald, 2002[26]; Ledwidge, 2003[27]	Unclear	High	Face-to-Face	MDS		x	x	x			Both	
Oddone, 1999[28]	Med	Med	Face-to-Face	PCP							Pre-d/c	

[a] Both = both pre- and post-d/c.

Abbreviations: d/c= discharge; HF = heart failure; MDS = multidisciplinary; Med = Medium; PCP = primary care (physician, nurse in clinic)

Table C5. Intervention Components for Clinic-based Interventions (Part 2)

Author, year	Risk of Bias	Individualized d/c plan	Provider continuity	Medications adjusted during inpatient stay	Planned telephone follow-up post d/c	Timing of first phone or TM follow-up (days)	Phone follow-up conducted by same personnel delivering inpatient intervention component	Series of structured calls	Patient phone hotline	Timing of first clinic visit post d/c (days)	Consultation with a dietician	Clinic personnel on-call/ available for acute symptom management (outside of scheduled appt)	Cardiac rehab component	Clinical pharmacist visit/ consultation	Medication optimization; pre-d/c or during intervention
Ekman, 1998[20]	Med				x	<7			x	NR		x			
Stromberg, 2003[21]	Low									> 14	x	x	x	x	
Ducharme, 2005[22]	Low				x	≤ 3		x		≤ 14	x	x		x	x
Kasper, 2002[23]	Low				x	≤ 7		x	x	Unclear					x
Liu, 2012[24]	Low	x			x	≤ 7	unclear	x	x	≤ 7	x	x			x
McDonald, 2001[25]; McDonald, 2002[26]; Ledwidge, 2003[27]	Unclear				x	<7	x	x	x	<14	x	x			
Oddone, 1999[28]	Med	x			x	1-2				<7					

Abbreviations: d/c= discharge; hrs = hours; Med = Medium; NR = not reported; TM= telemonitoring.

Table C6. Intervention Components for Other Interventions

Author, year	Specific Type of Intervention	Risk of Bias	Intensity	Primary Mode of Delivery	Delivery Personnel	Self-management education/ promotion	Weight-monitoring education or promotion	Diet/Sodium restriction education or promotion	Promotion of Medication Adherence	Exercise Education or promotion	Other or unspecified HF education	Medication Reconciliation	Setting/ Timing of Education [a]	Planned telephone follow-up post d/c	Timing of first phone or TM follow-up (days)	Phone follow-up conducted by same personnel delivering inpatient intervention component
Davis, 2012[29]	Other (Cognitive Training)	Med	Med	Face-to-Face	Nurse	x	x	x	x				Both	x	≤ 7	x
Riegel, 2004[30]	Other (Peer Support)	High	Med	Face-to-Face; Telephone	Peer Support	x	x	x	x				Post-d/c	x	<7	

[a] Both = both pre- and post-d/c.

Abbreviations: d/c= discharge; HF = heart failure; hrs = hours; Med = Medium.

Table C7. Intervention Components for STS Interventions (Part 1)

Author, year	Risk of Bias	Intensity	Primary Mode of Delivery	Delivery Personnel	Self-management education/ promotion	Weight-monitoring education or promotion	Diet/Sodium restriction education or promotion	Promotion of Medication Adherence	Exercise Education or promotion	Other or unspecified HF education	Medication Reconciliation	Setting/ Timing of Education [a]	Transition coach or coordination between inpatient/ outpatient providers
Angermann, 2011[31]	Med	High	Telephone; Face-to-Face	Nurse	x	x	x	x	x	x		Both	x
Barth, 2001[32]	High	Low	Telephone	Nurse	x	x	x	x	x		x	Post-d/c	
Cabezas, 2006[33]	Med	Med	Telephone; Face-to-Face	Pharmacist			x	x		x		Both	
Domingues, 2010[34]	Med	Low	Telephone	Nurse	x	x		x	x	x		Post-d/c	
Duffy, 2010[35]	High	Med	Face-to-Face; Telephone	Nurse	x	x		x		x		Post-d/c	
Dunagan, 2005[36]	Med	High	Telephone	Nurse	x	x	x	x	x		x	Post-d/c	
Jerant, 2001[37]; Jerant, 2003[38]	High	Med	Videophone; Telephone	Nurse	x	x	x	x				Both	
Laramee, 2003[39]	Med	High	Telephone; Face-to-Face	Nurse-Case Manager	x	x	x	x			x	Both	x
Rainville, 1999[40]	Med	Med	Telephone; Face-to-Face	Pharmacist		x		x		x		Both	x
Reigel, 2002[41]	Med	Med	Telephone	Nurse	x		x	x		x	x	Post-d/c	
Riegel, 2006[42]	Med	Med	Telephone	Nurse	x		x	x		x		Post-d/c	
Tsuyuki, 2004[43]	Med	High	Telephone	Nurse	x	x	x	x	x	x	x	Both	
Wakefield, 2008[44]; Wakefield, 2009[45]	Med	Med	Telephone	Nurse	x	x	x	x				Both	
Wakefield, 2008[44]; Wakefield, 2009[45]	Med	Med	Videophone	Nurse	x	x	x	x				Both	

[a] Both = both pre- and post-d/c.

Abbreviations: d/c= discharge; HF = heart failure; Med = Medium; STS = Structured Telephone Support.

Table C8. Intervention Components for STS Interventions (Part 2)

Author, year	Risk of Bias	Individualized d/c plan	Medications adjusted during inpatient stay	Planned telephone follow-up post d/c	Timing of first phone or TM follow-up (days)	Phone follow-up conducted by same personnel delivering inpatient intervention component	Series of structured calls	Patient phone hotline	Unspecified HF education/ promotion during home visit	Symptom checklist or Clinical Assessment during home visit *(e.g. history, symptoms)*	Timing of first clinic visit post d/c (days)	Clinical pharmacist visit/ consultation
Angermann, 2011[31]	Med			x	≤ 7	x	x	x				
Barth, 2001[32]	High			x	≤ 7		x	x				
Cabezas, 2006[33]	Med			x	≤ 7	unclear	x				≥ 14	x
Domingues, 2010[34]	Med			x	≤ 7		x					
Duffy, 2010[35]	High			x	NR		x	x	x	x		
Dunagan, 2005[36]	Med			x	≤ 7		x	x				
Jerant, 2001[37]; Jerant, 2003[38]	High			x	> 7	x	x	x				
Laramee, 2003[39]	Med	x		x	≤ 7	x	x	x				
Rainville, 1999[40]	Med		x	x	≤ 2	x	x	x				
Reigel, 2002[41]	Med			x	≤ 7		x					
Riegel, 2006[42]	Med			x	≤ 7		x					
Tsuyuki, 2004[43]	Med		x	x	≤14	x	x					
Wakefield, 2008[44]; Wakefield, 2009[45]	Med			x	≤ 7		x	x				
Wakefield, 2008[44]; Wakefield, 2009[45]	Med			x	≤ 7		x					

Abbreviations: CND = cannot determine; d/c= discharge; HF = heart failure; hrs = hours; Med = Medium; NR = not reported; STS = Structured Telephone Support; TM= telemonitoring.

Table C9. Intervention Components for STS Interventions (Part 3)

Author, year	Risk of Bias	Medication Optimization; Pre-d/c or During Intervention	Timing of First Tele-health Contact After d/c	Intervention Involves Reinforce-ment of d/c Plan	Prescribed Protocol Used to Guide Assessment And/or Plan	Telehealth Service Coordinates Care With Outpatient Provider	TM Device has Automated Adherence Reminder	Device Can Transmit Vital Signs	Device Can Transmit Symptoms	Device Utilizes Tech-nology That Allows Physical Exam
Angermann, 2011[31]	Med				x	x				
Barth, 2001[32]	High	x	≤ 7	x	x	x				
Cabezas, 2006[33]	Med			x						
Domingues, 2010[34]	Med									
Duffy, 2010[35]	High				x					
Dunagan, 2005[36]	Med					x			x	x
Jerant, 2001[37]; Jerant, 2003[38]	High		> 7		x			x	x	x
Laramee, 2003[39]	Med		≤ 7	x	x	x		x		
Rainville, 1999[40]	Med									
Reigel, 2002[41]	Med		≤ 7	x	x	x				
Riegel, 2006[42]	Med		≤ 7	x	x	x (as needed)				
Tsuyuki, 2004[43]	Med									
Wakefield, 2008[44]; Wakefield, 2009[45]	Med									
Wakefield, 2008[44]; Wakefield, 2009[45]	Med		≤ 7	x	x	x			x	x

Abbreviations: d/c= discharge; Med = Medium; STS = Structured Telephone Support; TM= telemonitoring.

Table C10. Intervention Components for Telemonitoring Interventions (Part 1)

Author, year	Risk of Bias	Intensity	Primary Mode of Delivery	Delivery Personnel	Self-management Education/ Promotion	Weight-Monitoring Education or Promotion	Diet/ Sodium Restriction Education or Promotion	Promotion of Medication Adherence	Exercise Education or Promotion	Other or unspecified HF education	Medication Reconciliation	Setting/ Timing of Education
Benatar, 2003[46]	Unclear	Med	Telephone	Nurse			x	x				Post-d/c
Dar, 2008[47]	Med	High	Remote monitoring	Nurse	x							Post-d/c
Dendale, 2012[48]	Unclear	Med	Remote monitoring	Nurse	x	x	x	x	x			Pre-d/c
Goldberg 2003[49]	Med	High	Remote monitoring	Nurse	x	x	x					Pre-d/c
Jerant, 2001[37]; Jerant, 2003[38]	High	Med	Videophone, telephone	Nurse	x	x	x	x				Post-d/c
Pekmezaris, 2012[50]	Med	Med	Videophone	Nurse	x		x	x				Post-d/c
Schwarz, 2008[51]	Med	Med	Remote monitoring	Nurse		x						Post-d/c
Woodend, 2008[52]	High	High	Remote monitoring and videophone	Nurse	x							Post-d/c

Abbreviations: d/c= discharge; HF = heart failure; Med = Medium.

Table C11. Intervention Components for Telemonitoring Interventions (Part 2)

Author, year	Risk of Bias	Transition Coach or Coordination Between Inpatient/ Outpatient Providers	Planned Telephone Follow-up Post d/c	Timing of First Phone or TM Follow-up (Days)	Phone Follow-up Conducted by Same Personnel Delivering Inpatient Intervention Component	Series of Struc-tured Calls	Patient Phone Hotline	Timing of First Home Visit (Days)	Number of Sche-duled Home Visits	Symptom Checklist or Clinical Assessment During Home Visit (e.g. History, Symptoms)	Physical Exam During Home Visit	Timing of First Clinic Visit Post d/c (Days)
Benatar, 2003[46]	Unclear	x										
Dar, 2008[47]	Med											
Dendale, 2012[48]	Unclear	x	x	≤ 7	x							> 14
Goldberg, 2003[49]	Med											
Jerant, 2001[37]; Jerant, 2003[38]	High		x	> 7		x	x	> 7	other	x		
Pekmezaris, 2012[50]	Med											
Schwarz, 2008[51]	Med							> 7	2 to 3		x	
Woodend, 2008[52]	High											

Abbreviations: d/c= discharge; Med = Medium; TM = telemonitoring.

Table C12. Intervention Components for Telemonitoring Interventions (Part 3)

Author, year	Risk of Bias	Clinic Personnel on-call/ Available for Acute Symptom Management *(Outside of Scheduled Appt)*	Timing of First Telehealth Contact After d/c (Days)	Intervention Involves Reinforce-ment of d/c Plan	Prescribed Protocol Used to Guide assessment and/or Plan	Telehealth Service Coordinates Care With Outpatient Provider	TM Device has Auto-mated Ad-herence Remin-der	Device can Transmit Vital Signs	Device can Transmit Symp-toms	Device Utilizes Techno-logy that Allows Physical Exam
Benatar, 2003[46]	Unclear		> 7		x			x		
Dar, 2008[47]	Med				x			x	x	
Dendale, 2012[48]	Unclear	x	≤1					x		
Goldberg 2003[49]	Med		> 7	x	x	x	x	x	x	
Jerant, 2001[37]; Jerant, 2003[38]	High		> 7		x			x	x	x
Pekmezaris, 2012[50]	Med		> 7					x		x
Schwarz, 2008[51]	Med				x	x		x	x	
Woodend, 2008[52]	High		1-2		x			x		x

Abbreviations: appt = appointment; d/c= discharge; hrs = hours; Med = Medium; TM = telemonitoring.

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Appendix D. Risk of Bias Evaluations and Rationale

Author, Year Trial name[a]	Randomization method adequate?	Allocation concealment adequate?	Are groups similar at baseline?	Outcome assessors blinded?	Overall attrition Differential attrition	Does high attrition rate raise concern for bias?	Intervention fidelity adequate?	ITT Analysis? Appropriate method for handling missing data?	Utilization outcomes: valid, reliable, consistent?	Health and social outcomes: valid, reliable, consistent?	Risk of bias Rationale for rating
Albert, 2007[1]	Yes	Yes	No	NR/CND	19% lost to follow-up; 29% died or were lost to follow-up 1.1% loss to follow-up; 6% differential attrition when counting those who either died or were lost to follow-up	Yes	Yes	Yes No	NR/CND	NR/CND	High Baseline characteristics not similar (more women in the usual care group, more smokers in the intervention group). Inadequate method of handling missing data (completer's analysis). No information given on how mortality or health care utilization outcomes measured.
Aldamiz-Echevarría Iraúrgui, 2007[2]	Yes	Yes	Yes	NR/CND	0% 0%	No	NR/CND	Yes NA	Yes	Yes	Medium

Author, Year Trial name[a]	Randomization method adequate?	Allocation concealment adequate?	Are groups similar at baseline?	Outcome assessors blinded?	Overall attrition Differential attrition	Does high attrition rate raise concern for bias?	Intervention fidelity adequate?	ITT Analysis? Appropriate method for handling missing data?	Utilization outcomes: valid, reliable, consistent?	Health and social outcomes: valid, reliable, consistent?	Risk of bias Rationale for rating
Angermann, 2012[3]	Yes	NR/CND	Yes	Yes	0% for mortality and utilization outcomes; no QoL available for those who died or did not complete a follow-up phone call (58%) NA for mortality/ utilization; unclear for QoL	No	NR/CND	Yes Yes	Yes	Yes	Medium
Barth, 2001[4]	NR/CND	NR/CND	Yes	NR/CND	0% NA	No	NR/CND	Unclear or NR NA	Unclear	Yes	High High risk of selection bias; unclear how the 34 participants were recruited from the overall population. Methods used to measure utilization outcomes were not described.

Author, Year Trial name[a]	Randomization method adequate?	Allocation concealment adequate?	Are groups similar at baseline?	Outcome assessors blinded?	Overall attrition Differential attrition	Does high attrition rate raise concern for bias?	Intervention fidelity adequate?	ITT Analysis? Appropriate method for handling missing data?	Utilization outcomes: valid, reliable, consistent?	Health and social outcomes: valid, reliable, consistent?	Risk of bias Rationale for rating
Benatar, 2003[5]	NR/CND	NR/CND	Yes, for age, sex, race, NYHA, EF; higher proportions with DM, ACEI use, BB use in NTM group	NR/CND	0% (3 ms) 0% (3 ms)	No	NR/CND	Unclear or NR NA for 3 ms; NR beyond that	NR/CND	Yes	Unclear (utilization outcomes); Medium (QoL) Rated unclear for utilization outcomes; ascertainment NR. Measures for QoL, psychological distress, and self-efficacy more clearly described and used validated measures. Masking of outcome assessors NR. Methods or randomization and allocation concealment NR. Although study reports that all randomized patients completed at least 3 months, no flow chart or data included to report attrition over the course of the study. Whether ITT analysis used NR. Unclear how missing data handled (and how much there was) beyond 3 months. Potential COI with senior author as developer of the hardware and software.

Author, Year Trial name[a]	Randomization method adequate?	Allocation concealment adequate?	Are groups similar at baseline?	Outcome assessors blinded?	Overall attrition Differential attrition	Does high attrition rate raise concern for bias?	Intervention fidelity adequate?	ITT Analysis? Appropriate method for handling missing data?	Utilization outcomes: valid, reliable, consistent?	Health and social outcomes: valid, reliable, consistent?	Risk of bias Rationale for rating
Cabezas, 2006[6]	NR/CND	NR/CND	Yes	NR/CND	0%; no QoL outcomes for 13% who died at 6 months 0%; 10% when including deaths at 6 months	No	NR/CND	Unclear or NR NA	Yes	Yes	Medium
Dar, 2009[7]	Yes	Yes	Yes	NR/CND	0% 0%	No	Yes	Yes Yes	Yes	Yes	Medium
Davis, 2012[8]	NR/CND	NR/CND	Yes	Yes	13% 0%	No	NR/CND	Yes Yes	Yes	Yes	Medium
Dendale, 2012[9]	NR/CND	Yes	Yes	Yes	0% 0%	No	NR/CND	Yes NA	NR	Yes	Unclear Unclear fidelity- study reports that 76% of the GPs logged into the website at least once during the study. Unclear if the GPs could receive patient alerts outside of the website. It is unclear how utilization outcomes were measured; no specific information is given.
Domingues, 2011[10]	NR/CND	NR/CND	Yes	NR/CND	4% 3%	No	Yes	Yes No	Yes	NA	Medium

Author, Year Trial name[a]	Randomization method adequate?	Allocation concealment adequate?	Are groups similar at baseline?	Outcome assessors blinded?	Overall attrition Differential attrition	Does high attrition rate raise concern for bias?	Intervention fidelity adequate?	ITT Analysis? Appropriate method for handling missing data?	Utilization outcomes: valid, reliable, consistent?	Health and social outcomes: valid, reliable, consistent?	Risk of bias Rationale for rating
Ducharme, 2005[11]	Yes	Yes	Yes	Yes for QoL, No for utilization outcomes.	0% 0%	NA	Yes	Yes NA	Yes	Yes	Low
Duffy, 2010[12]	No	No	NR/CND	NR/CND	NR/CND NR/CND	Unclear or NR	NR/CND	Unclear or NR NA	unclear	Yes	High Sample characteristics not given for separate arms; in the text, noted that there were no differences. Unclear if the database used to capture healthcare utilization is comprehensive or based on only nurse input of known utilization. Control arm poorly described and received nearly as many home visits as the intervention group.

Author, Year Trial name[a]	Randomization method adequate?	Allocation concealment adequate?	Are groups similar at baseline?	Outcome assessors blinded?	Overall attrition Differential attrition	Does high attrition rate raise concern for bias?	Intervention fidelity adequate?	ITT Analysis? Appropriate method for handling missing data?	Utilization outcomes: valid, reliable, consistent?	Health and social outcomes: valid, reliable, consistent?	Risk of bias Rationale for rating
Dunagan, 2005[13]	Yes	NR/CND	Yes	Yes	0% for utilization outcomes; see Risk of bias/Rationale for rating column for QoL 0% for utilization outcomes; see Risk of bias/Rationale for rating column for QoL	No	NR/CND	Yes NA for utilization outcomes; no for QoL outcomes	Yes	Yes	Medium Would be reasonable to call this Low RoB for utilization outcomes, and Medium for QoL. Note on attrition: in the results, reported that 0 patients lost to follow-up and all included in the analyses, except where specifically noted, and no notes that any patients were not included for the main outcomes. However, in Methods, authors report that some patients did not complete 6-month and 12-month questionnaire, so there was some attrition and missing data for the QOL outcomes, and completers analysis apparently used for those outcomes (66/75 analyzed for control group; and 64/76 for intervention group at 6 months.
Ekman, 1998[14]	Yes	Yes	For most characteristics, however more patients in usual care group had AF	NR/CND	0% NA	No	NR/CND	Yes NA	Yes	Yes	Medium

Author, Year Trial name[a]	Randomization method adequate?	Allocation concealment adequate?	Are groups similar at baseline?	Outcome assessors blinded?	Overall attrition Differential attrition	Does high attrition rate raise concern for bias?	Intervention fidelity adequate?	ITT Analysis? Appropriate method for handling missing data?	Utilization outcomes: valid, reliable, consistent?	Health and social outcomes: valid, reliable, consistent?	Risk of bias Rationale for rating
Goldberg, 2003[15]	NR/CND	NR/CND	Yes	Yes	11.4% CND, but article reports that there was no difference between groups in % of patients who failed to complete 6 months	No	Yes	Yes NR/CND for utilization (likely censored); completers analysis for health and social outcomes	Yes	Yes	Medium
Holland, 2007[16]	Yes	NR/CND	No	NR/CND	1% 0%	No	Yes	Yes NA	Yes	Yes	Medium At baseline, the intervention group utilized more aids to assist with medication adherence, and fewer participants in the intervention group were from a non-manual social class.
Jaarsma, 1999[17]	NR/CND	NR/CND	Yes	No	5% "non-response" rate; 17% of sample died 0% for loss to follow-up	No	NR/CND	Yes Unclear	Yes	Yes	Medium

Author, Year Trial name[a]	Randomization method adequate?	Allocation concealment adequate?	Are groups similar at baseline?	Outcome assessors blinded?	Overall attrition Differential attrition	Does high attrition rate raise concern for bias?	Intervention fidelity adequate?	ITT Analysis? Appropriate method for handling missing data?	Utilization outcomes: valid, reliable, consistent?	Health and social outcomes: valid, reliable, consistent?	Risk of bias Rationale for rating
Jerant, 2001[18] Jerant, 2003[19]	Yes	Yes	Yes	No	0% 0%	No	No	Yes NA	Yes	Yes	High Small study (37 participants) that suffers from concerns regarding intervention fidelity. Authors note that at least one technical problem affected 76% of all telemonitoring encounters.
Kasper 2002[20]	Yes	NR/CND	Yes	Yes	0% 0%	No	Yes	Yes NA	Yes	Yes	Low
Kimmelstiel, 2004[21]	NR/CND	NR/CND	Yes	Yes	4.5% due to death at 12 weeks NR	No	Yes	Yes NA	Yes	Yes	Medium
Koelling, 2005[22]	Yes	Yes	Yes	Yes	0.0% 0.0%	No	Yes	Yes NA	Yes	Yes	Low
Kwok, 2007[23]	Yes	NR/CND	No	Yes for functional status; unclear for utilization rates	2.8% 1.5%	No	NR/CND	Yes NR/CND	Yes	Yes	Medium Intervention group had more participants receiving "comprehensive social security assistance." Regional hospital database searched to assess utilization outcomes; two patients excluded because they moved away from Hong Kong.

Author, Year Trial name[a]	Randomization method adequate?	Allocation concealment adequate?	Are groups similar at baseline?	Outcome assessors blinded?	Overall attrition Differential attrition	Does high attrition rate raise concern for bias?	Intervention fidelity adequate?	ITT Analysis? Appropriate method for handling missing data?	Utilization outcomes: valid, reliable, consistent?	Health and social outcomes: valid, reliable, consistent?	Risk of bias Rationale for rating
Laramee, 2003[24] RCT	Yes	NR/CND	Yes, for most, but some differences for PVD, class I and II NYHA, prior CHF admissions, and readmission risk factors	No	8.7% 8.8%	No	NR/CND	Yes No	Yes	Yes	Medium Moderate risk of selection bias and confounding. No masking of outcome assessors reported. Inadequate handling of missing data (although little missing data). Intervention group had baseline higher risk for readmission, and study found no benefit of intervention. However, logistic regression controlling for patient severity still found no difference for readmissions.

Author, Year Trial name[a]	Randomization method adequate?	Allocation concealment adequate?	Are groups similar at baseline?	Outcome assessors blinded?	Overall attrition Differential attrition	Does high attrition rate raise concern for bias?	Intervention fidelity adequate?	ITT Analysis? Appropriate method for handling missing data?	Utilization outcomes: valid, reliable, consistent?	Health and social outcomes: valid, reliable, consistent?	Risk of bias Rationale for rating
Linne, 2006[25]	Yes	Yes	Yes, for most characteristics	Yes	2.6% 1.4%	No	NR/CND	Yes NR/CND	NR/CND	NR/CND	Unclear Unclear risk of bias, mainly due to inadequate reporting of information to allow complete assessment of risk of measurement bias. Groups similar at baseline Unclear how missing data handled, but very few subjects had missing outcome data (2/108 and 4/122 refused to participate further in the control and intervention groups, respectively), so likely minimal potential impact. They were likely censored in the survival analysis. Unclear risk of measurement bias: authors only report that they used "an administrative system, PAS, ... to verify all-cause readmissions and deaths within 6 months from discharge." Study conducted in Sweden, and no additional information about validity and reliability of that system's readmission and death information.

Author, Year Trial name[a]	Randomization method adequate?	Allocation concealment adequate?	Are groups similar at baseline?	Outcome assessors blinded?	Overall attrition Differential attrition	Does high attrition rate raise concern for bias?	Intervention fidelity adequate?	ITT Analysis? Appropriate method for handling missing data?	Utilization outcomes: valid, reliable, consistent?	Health and social outcomes: valid, reliable, consistent?	Risk of bias Rationale for rating
Liu, 2012[26]	Yes	NR/CND	Yes	Yes	0.00% 0%	No	NR/CND	Yes NA	Yes	Yes	Low
McDonald, 2001[27] McDonald, 2002[28] Ledwidge, 2003[29]	NR/CND	NR/CND	Yes	NR/CND	0% 0%	No	NR/CND	Yes NA	Unclear	Unclear for mortality; Yes for social outcomes	Unclear Unclear measurement bias. Method of outcome assessment (measurement of mortality and utilization) not described and unclear.
Naylor, 2004[30]	Yes	Yes	Yes	Yes	20.5% 1.4%	No	NR/CND	Yes Yes	Yes	Yes	Low
Nucifora, 2006[31]	NR/CND	NR/CND	No	NR/CND	0% lost to follow-up; 11% died 0% NA for missing data; 6% for deaths	No	NR/CND	Yes Yes	Yes	Yes	Medium More patients in "usual care" group had AF and were on digitalis compared with intervention group.
Oddone, 1999[32]	NR/CND	NR/CND	Yes	Yes	NR/CND NR	Unclear or NR	Yes	Unclear or NR Unclear or NR	Yes	Yes	Medium Patients excluded from this analysis who were initially enrolled if they had insufficient data for analysis or for whom chart not available.
Pekmezaris 2012[33]	Yes	NR/CND	Yes	NR/CND	0% 0%	No	Yes	Yes Yes	Yes	NA	Medium

Author, Year Trial name[a]	Randomization method adequate?	Allocation concealment adequate?	Are groups similar at baseline?	Outcome assessors blinded?	Overall attrition Differential attrition	Does high attrition rate raise concern for bias?	Intervention fidelity adequate?	ITT Analysis? Appropriate method for handling missing data?	Utilization outcomes: valid, reliable, consistent?	Health and social outcomes: valid, reliable, consistent?	Risk of bias Rationale for rating
Pugh, 2001[34]	NR/CND	NR/CND	Yes	NR/CND	10% due to withdrew; 29% died or withdrew 1%	No	NR/CND	Unclear or NR No	Unclear	Yes	High Patients who withdrew or who died appear to be excluded from the readmission/ utilization analysis. Unclear if 11 patients who died had also experienced a readmission or ER visit during study. NR whether those who withdrew were contacted and asked about health care utilization. Randomization and allocation concealment not described.
Rainville, 1999[35]	Yes	NR/CND	No	NR/CND	14% died; no loss to follow-up reported after randomization 0% for loss to follow-up; 17% for death	Yes	NR/CND	Unclear or NR No	Yes	Yes	Medium Patients in control group slightly older. More deaths in intervention compared with control; however, this was a primary outcome.
Rich, 1993[36]	NR/CND	NR/CND	Yes	NR/CND	0% 0%	No	NR/CND	Unclear or NR NA	Yes	NA	Medium

Author, Year Trial name[a]	Randomization method adequate?	Allocation concealment adequate?	Are groups similar at baseline?	Outcome assessors blinded?	Overall attrition Differential attrition	Does high attrition rate raise concern for bias?	Intervention fidelity adequate?	ITT Analysis? Appropriate method for handling missing data?	Utilization outcomes: valid, reliable, consistent?	Health and social outcomes: valid, reliable, consistent?	Risk of bias Rationale for rating
Rich, 1995[37]	Yes	Yes	No	NR/CND	0% 0%	No	NR/CND	Yes NA	Unclear	Yes	Medium Detailed information on how utilization outcomes were assessed not provided.
Riegel 2002[38]	No	NR/CND	No	NR/CND	0% for outcomes of interest (acute care resources) NA	No	Yes	Unclear or NR NA	Yes	NA	Medium Subjects randomized to intervention group had a higher rate of beta-blocker use at discharge and lower prevalence of COPD. Randomization at level of provider, but data analysis occurred at patient level.

Author, Year Trial name[a]	Randomization method adequate?	Allocation concealment adequate?	Are groups similar at baseline?	Outcome assessors blinded?	Overall attrition Differential attrition	Does high attrition rate raise concern for bias?	Intervention fidelity adequate?	ITT Analysis? Appropriate method for handling missing data?	Utilization outcomes: valid, reliable, consistent?	Health and social outcomes: valid, reliable, consistent?	Risk of bias Rationale for rating
Riegel, 2004[39]	Yes	NR/CND	No	NR/CND	31.8% 1.5%	Yes	Yes	Yes for utilization outcome; no for self-care/social outcomes (those were completer's analysis) No	NR/CND	NR/CND for mortality; Yes for self-care measures	High High risk of selection bias, measurement bias, and confounding. Over 30% of sample dropped out, high attrition; methods of handling missing data NR for utilization outcomes. Unclear how utilization outcomes were ascertained, and unclear how complete data was for utilization outcomes (focus of study on self-care and social support outcomes). Masking of outcome assessors NR. Several baseline differences between groups: fewer married in intervention group, fewer retired, fewer with stage 3/4 NYHA when collapsing those groups (57% vs. 69%), fewer with COPD and history of MI.

Author, Year Trial name[a]	Randomization method adequate?	Allocation concealment adequate?	Are groups similar at baseline?	Outcome assessors blinded?	Overall attrition Differential attrition	Does high attrition rate raise concern for bias?	Intervention fidelity adequate?	ITT Analysis? Appropriate method for handling missing data?	Utilization outcomes: valid, reliable, consistent?	Health and social outcomes: valid, reliable, consistent?	Risk of bias Rationale for rating
Riegel, 2006[40]	NR/CND	Yes	Yes	Yes	0.0% 0.0%	No	Yes	Yes NA	Yes	Yes	Medium Rated medium risk of bias, but favorable responses for almost all fields. Authors did not report randomization information to determine if method was adequate. Fidelity: 82.9% of intervention group received the full 6-ms intervention. No missing data as no patients lost to follow up; 1 subject in intervention group excluded from analysis as "outlier".
Schwarz, 2008[41]	NR/CND	NR/CND	No	NR/CND	21% including death, nursing home and withdrawal from study; appears that mortality and utilization outcomes were available for full sample. 8%	No	Yes	Yes Yes	Yes	Yes	Medium More participants in intervention group were high school graduate or higher. Utilization outcomes measured via record review, and unclear if this also included patient report.

Author, Year Trial name[a]	Randomization method adequate?	Allocation concealment adequate?	Are groups similar at baseline?	Outcome assessors blinded?	Overall attrition Differential attrition	Does high attrition rate raise concern for bias?	Intervention fidelity adequate?	ITT Analysis? Appropriate method for handling missing data?	Utilization outcomes: valid, reliable, consistent?	Health and social outcomes: valid, reliable, consistent?	Risk of bias Rationale for rating
Sethares, 2004[42]	NR/CND	NR/CND	Yes	Mixed (yes for readmission, no for QoL for the intervention group)	20.5% CND	Yes	NR/CND	No No	Yes	Yes	High High risk of selection bias and confounding. Completers analysis, 18/88 post-randomization exclusions due to death (10) or missing data (8); analysis only included 70 subjects who did not die and not lost to follow-up. Unclear why more detailed assessments of the 10 deaths not included in analysis. No reporting of which groups the 18 post-randomization exclusions were in to allow determination of differential attrition. The 10 deaths, if adequately assessed for readmission and attributed to appropriate study groups, could significantly change results, since only 6 people readmitted in intervention group and 12 in control group. Inadequate handling of missing data; methods of randomization and allocation concealment NR

Author, Year Trial name[a]	Randomization method adequate?	Allocation concealment adequate?	Are groups similar at baseline?	Outcome assessors blinded?	Overall attrition Differential attrition	Does high attrition rate raise concern for bias?	Intervention fidelity adequate?	ITT Analysis? Appropriate method for handling missing data?	Utilization outcomes: valid, reliable, consistent?	Health and social outcomes: valid, reliable, consistent?	Risk of bias Rationale for rating
Stewart, 1998[43]	No	NR/CND	Yes	NR/CND	NR/CND; appears to be mortality and utilization outcomes on all participants NA	Unclear or NR	Yes	Yes NA	Yes	Yes	Medium
Stewart, 1999[44]	Yes	Yes	Yes	Yes	NR/CND; 10% of the intervention group withdrew and unclear how missing data handled 10% of intervention group withdrew; attrition NR for usual care group	No	NR/CND	Yes Unclear	Yes	Yes	Medium 10% of intervention group withdrew post-discharge (refused home visits). Unclear whether these patients included in primary analyses.

Author, Year Trial name[a]	Randomization method adequate?	Allocation concealment adequate?	Are groups similar at baseline?	Outcome assessors blinded?	Overall attrition Differential attrition	Does high attrition rate raise concern for bias?	Intervention fidelity adequate?	ITT Analysis? Appropriate method for handling missing data?	Utilization outcomes: valid, reliable, consistent?	Health and social outcomes: valid, reliable, consistent?	Risk of bias Rationale for rating
Stromberg, 2003[45]	Yes	Yes	Yes, for most (but more with HTN in intervenetion group and fewer with DM)	Yes	0% lost to follow-up; 15% died before 3 months 0% lost to follow-up; 18% for deaths by 3 months	No	Yes	Yes Yes	Yes	Yes	Low Patients who died were censored in analysis.
Thompson, 2005[46]	NR/CND	NR/CND	No	Yes	0% for utilization outcomes; 57% for QoL 0% for utilization outcomes; NR/CND for QoL	Yes (QoL only)	Yes	Yes No (no for QoL only)	Yes	Yes	High Study used cluster randomization according to treating GP, resulting in important baseline differences between groups; analysis done at patient level. Higher proportion of diabetes (27% vs. 14%) and lower proportion of medication use for ACEIs, BBs, Aspirin, and warfarin at time of hospital discharge for control group than intervention group. Thus, control group at higher risk of readmissions and death than intervention group. QoL outcome data have high risk of bias due to very high attrition, with fewer than half of subjects returning questionnaire.

Author, Year Trial name[a]	Randomization method adequate?	Allocation concealment adequate?	Are groups similar at baseline?	Outcome assessors blinded?	Overall attrition Differential attrition	Does high attrition rate raise concern for bias?	Intervention fidelity adequate?	ITT Analysis? Appropriate method for handling missing data?	Utilization outcomes: valid, reliable, consistent?	Health and social outcomes: valid, reliable, consistent?	Risk of bias Rationale for rating
Triller, 2008[47]	Yes	Yes	Yes	NR/CND	0% NA	No	No	Yes NA	Unclear	No	Unclear No information provided on method used to measure readmission and other utilization outcomes. Neither type of QoL measured nor QoL scale used are described, making validity of those data unclear. Only 53% of sample received full 3 visits from a pharmacist. Unclear fidelity.
Tsuyuki, 2004[48]	Yes	NR/CND	Yes	No	2.5% 0.8%	No	NR/CND	Yes NR/CND	Yes	Yes	Medium
Wakefield, 2008[49] Wakefield, 2009[50]	NR/CND	NR/CND	Yes	NR/CND	0% for readmission and mortality; 26% for QoL or self-care burden NA for mortality/ utilization outcomes; 6% for self-care burden outcome	No	Unclear	Yes NA	Yes	Yes	Medium 25% of videophone contacts conducted via telephone due to technical difficulties.

Author, Year Trial name[a]	Randomization method adequate?	Allocation concealment adequate?	Are groups similar at baseline?	Outcome assessors blinded?	Overall attrition Differential attrition	Does high attrition rate raise concern for bias?	Intervention fidelity adequate?	ITT Analysis? Appropriate method for handling missing data?	Utilization outcomes: valid, reliable, consistent?	Health and social outcomes: valid, reliable, consistent?	Risk of bias Rationale for rating
Woodend, 2008[51]	NR/CND	NR/CND	No	NR/CND	NR/CND at eligible time points NR/CND	Unclear or NR	NR/CND	Yes NR/CND	No	unclear	High Fewer patients in telemonitoring group had angina compared with usual care. Loss to follow-up and death reported for 12 months, unclear if these were included in data analysis for earlier time points or excluded. At 12 months, 22% of the intervention group also received home visits. Utilization outcomes assessed by self-report only. Not clear if attempt made to account for utilization among those lost to follow-up or who were later found to have died.

[a] Three studies involved crossover designs or contamination: Duffy, 2010,[12] Pekmezaris, 2012[33] and Woodend, 2008.[51]

Abbreviations: ACEI = ACE inhibitor; AF = atrial fibrillation; BB = beta-blocker; CND = cannot determine; COI = conflict of interest; COPD = chronic obstructive pulmonary disease; DM = diabetes mellitus; EF = ejection fraction; ER = emergency room; GP = general practitioner; CHF = congestive heart failure; HTN = hypertension; ITT = intent-to-treat; MI = myocardial infarction; Ms = months; NA = not applicable; NR = not reported; NTM = no telemonitoring; NYHA = New York Heart Association functional classification; PVD = peripheral vascular disease; QoL = quality of life; RoB = risk of bias; vs. = versus

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Appendix E. Meta-Analysis

Figure E-1. All-cause readmission for transitional care interventions compared with usual care, by intervention category and outcome timing

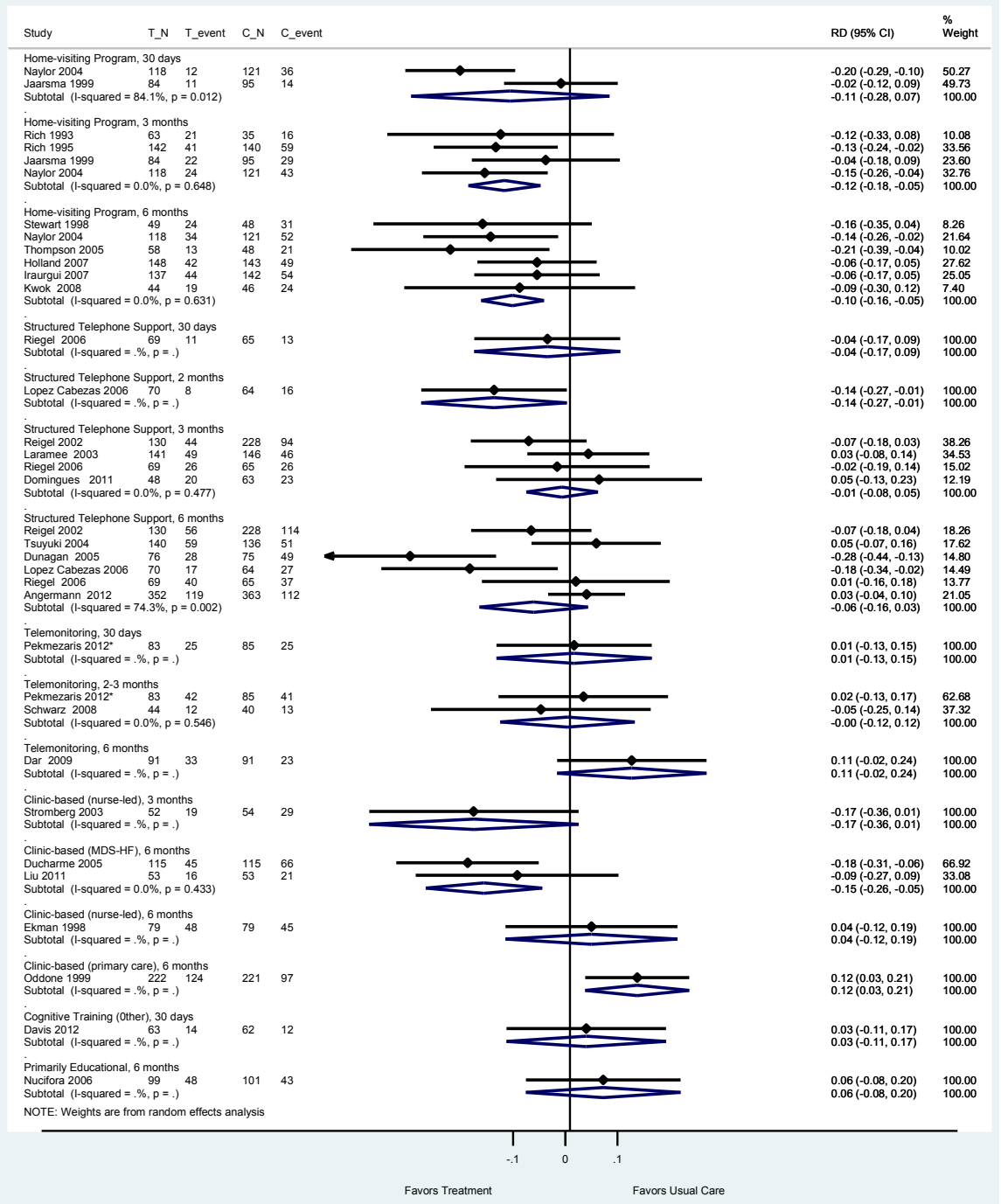


Figure E-2. Heart failure readmissions for transitional care interventions compared with usual care, by intervention category and outcome timing

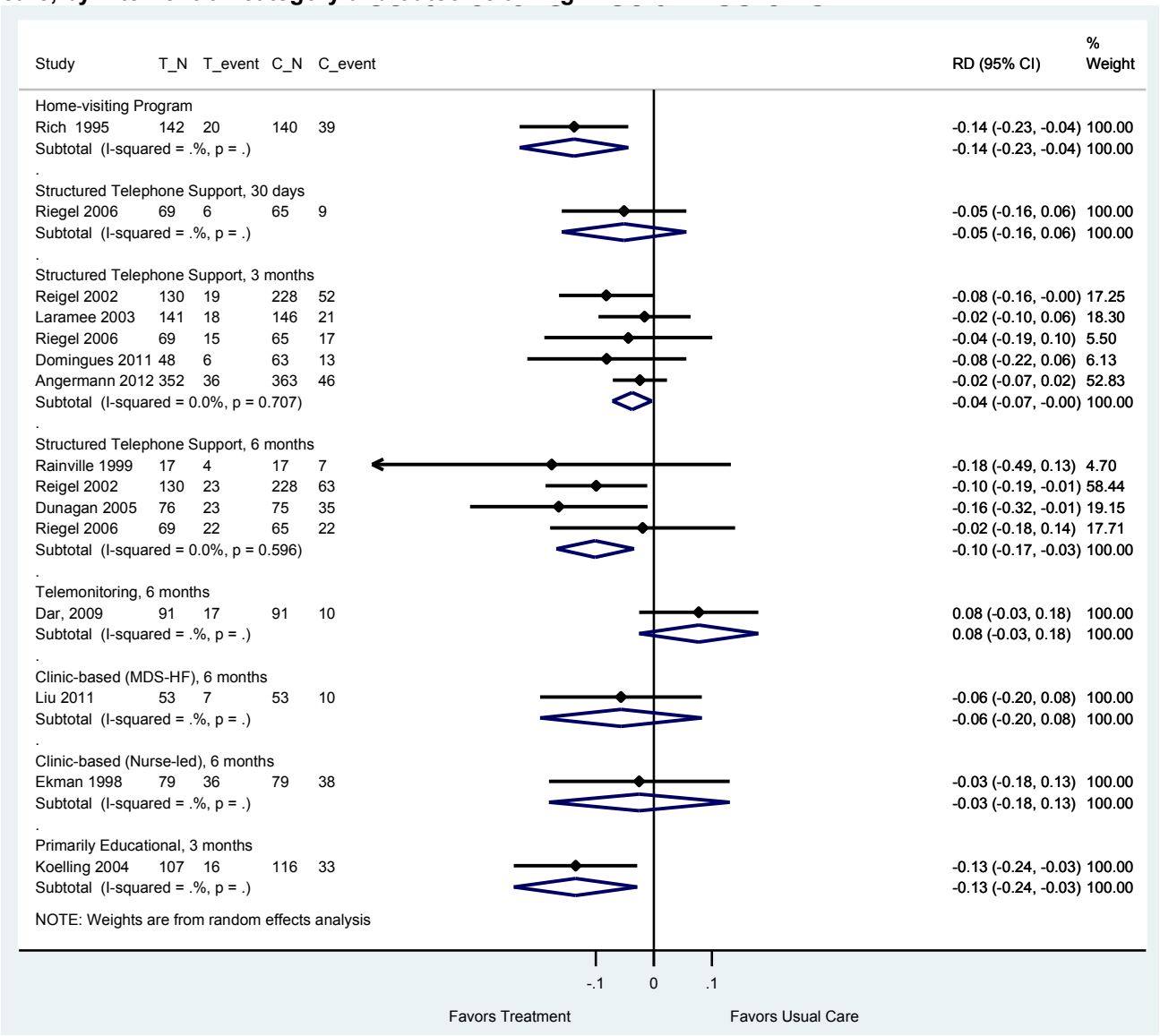


Figure E-3. Combined all-cause readmission or death for transitional care interventions compared with usual care, by intervention category and outcome timing

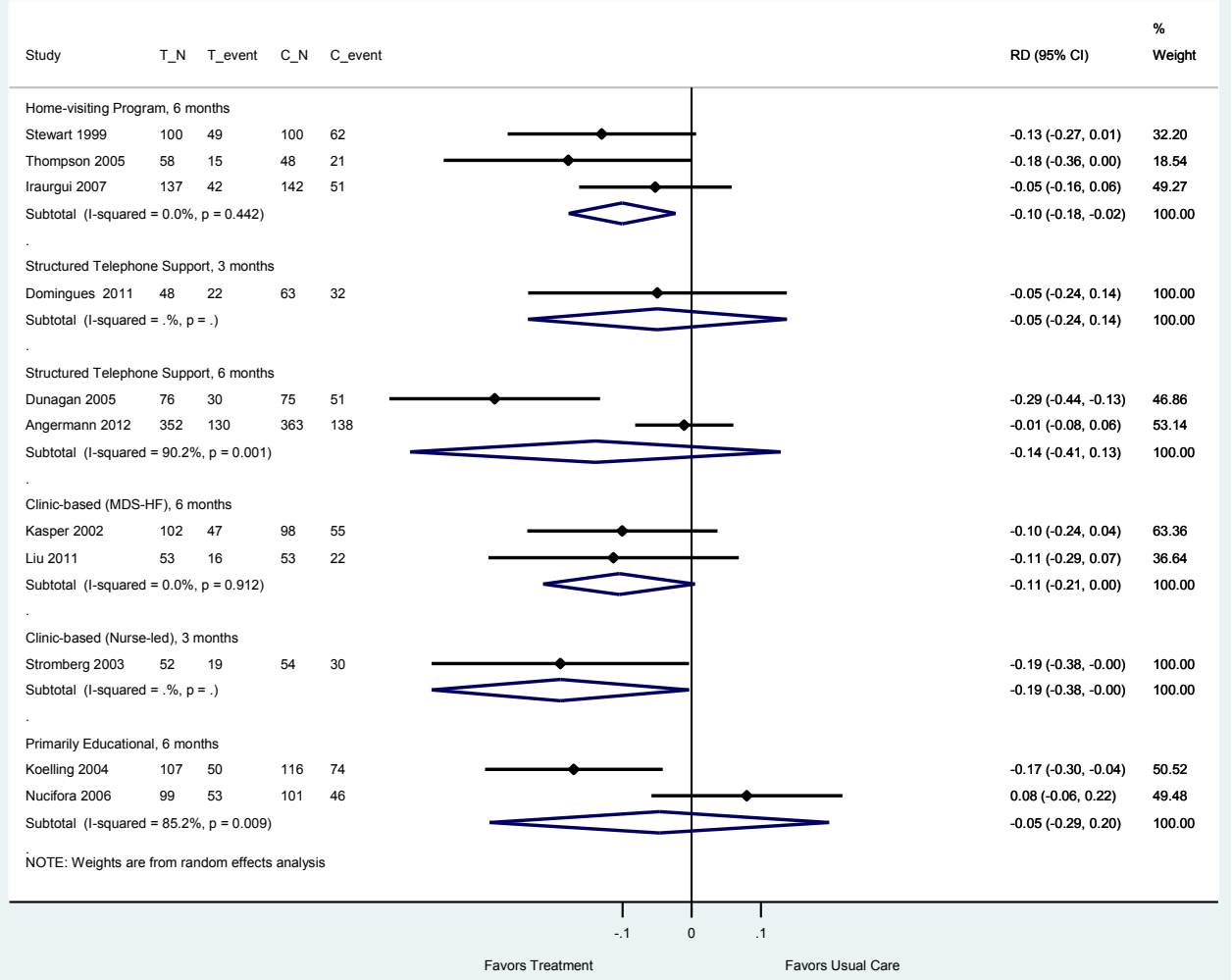


Figure E-4. Mean hospital days per person (of subsequent readmissions) for home-visiting programs compared with usual care over 3 months

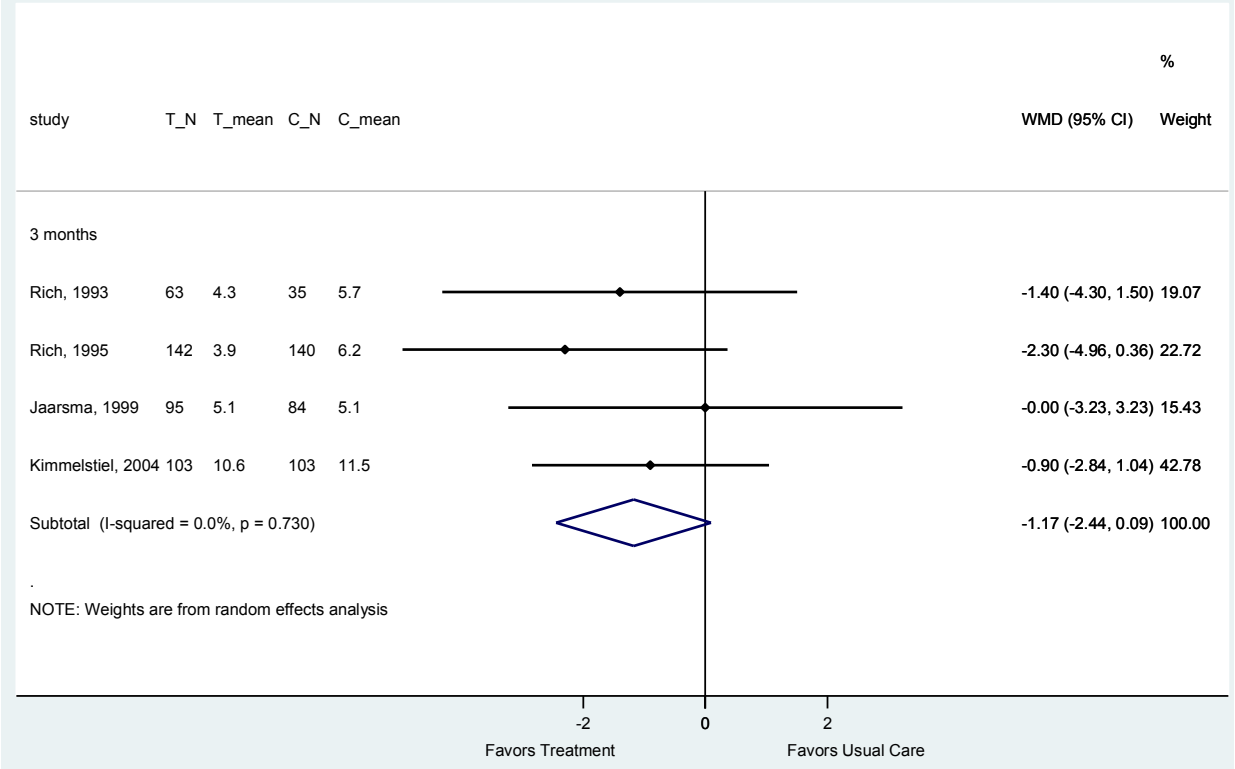


Figure E-5. Total hospital days per group (of subsequent readmissions) for structured telephone

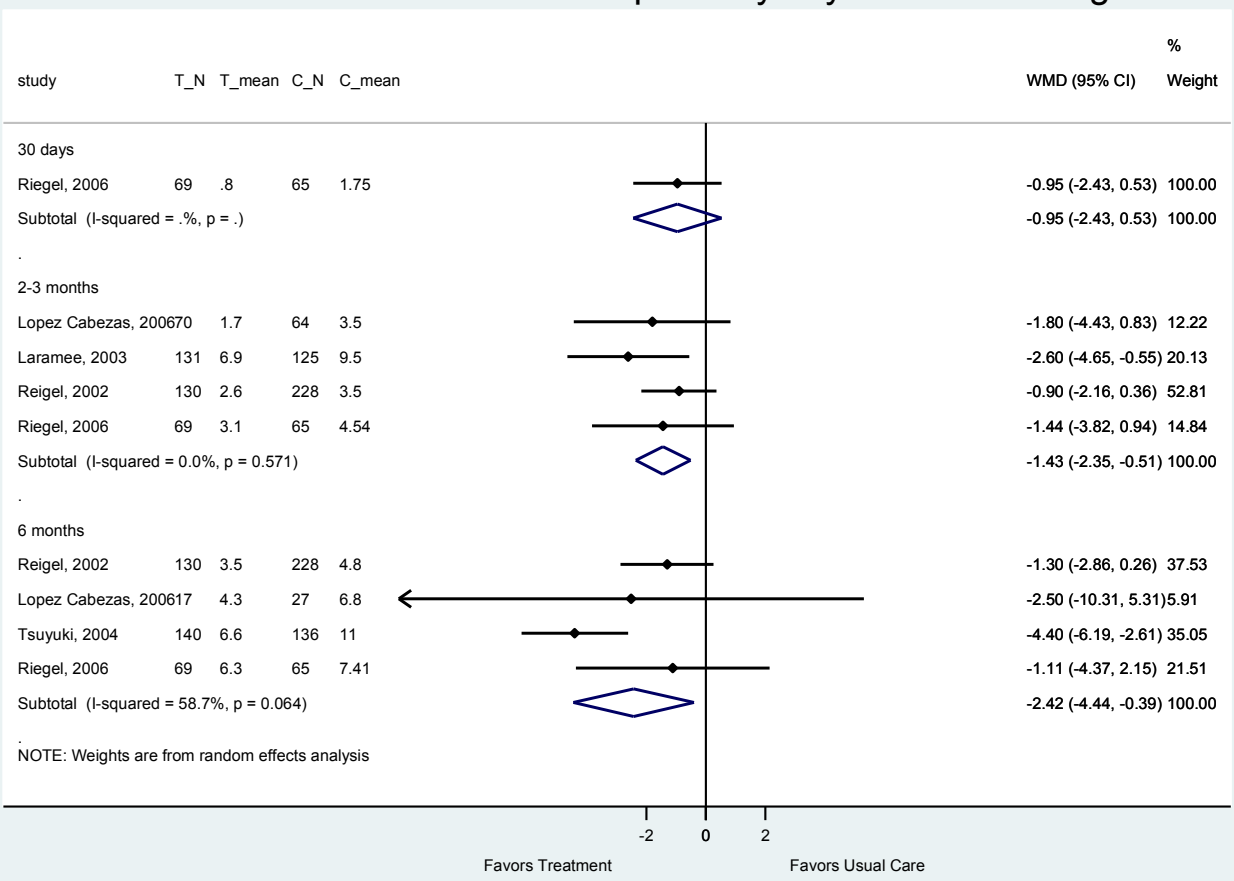


Figure E-6. Mortality among patients receiving transitional care interventions compared with usual care, by intervention category and outcome timing

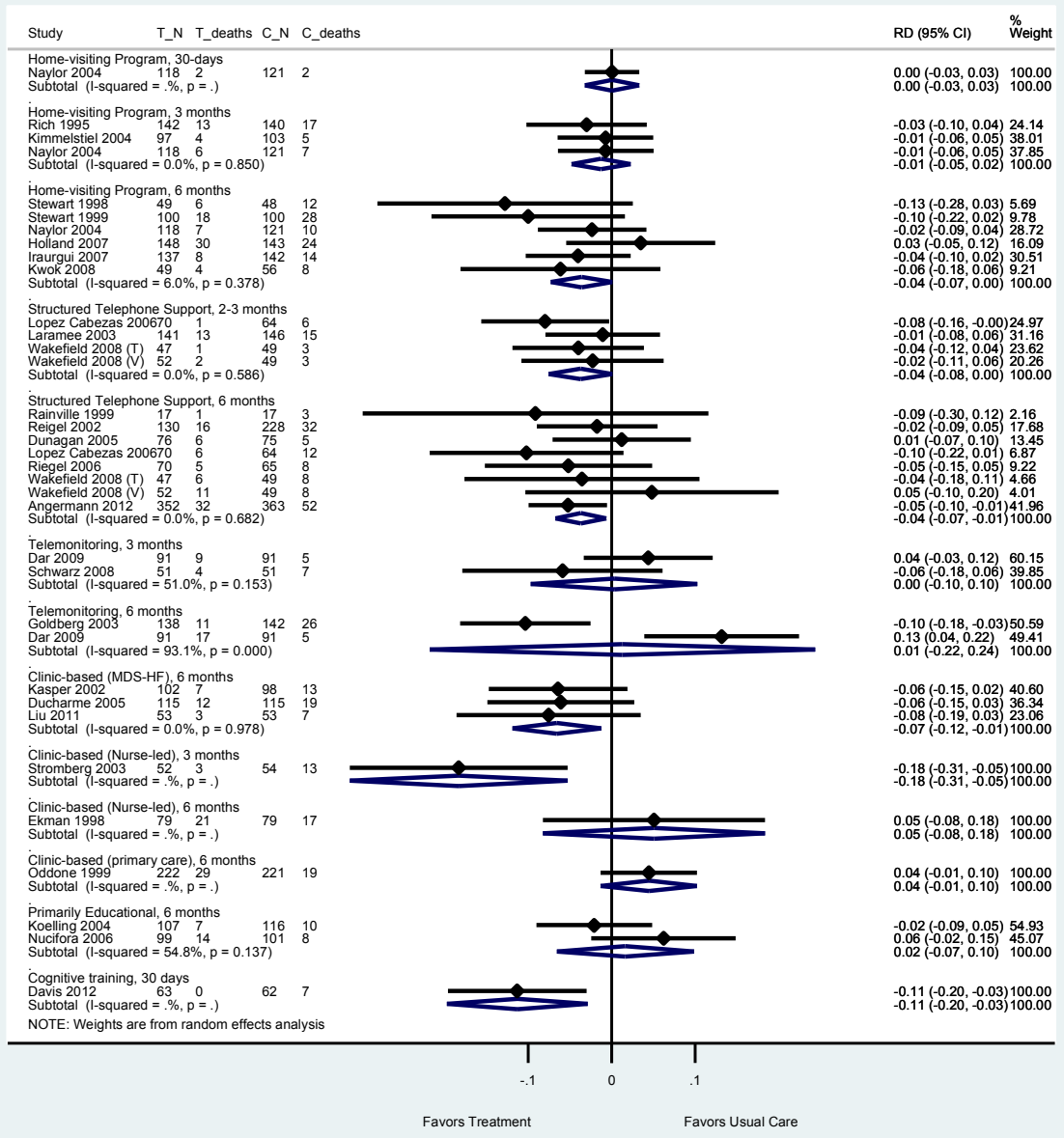


Figure E-7. Difference in mean MLWHFQ scores for home-visiting programs compared with usual care, by outcome timing

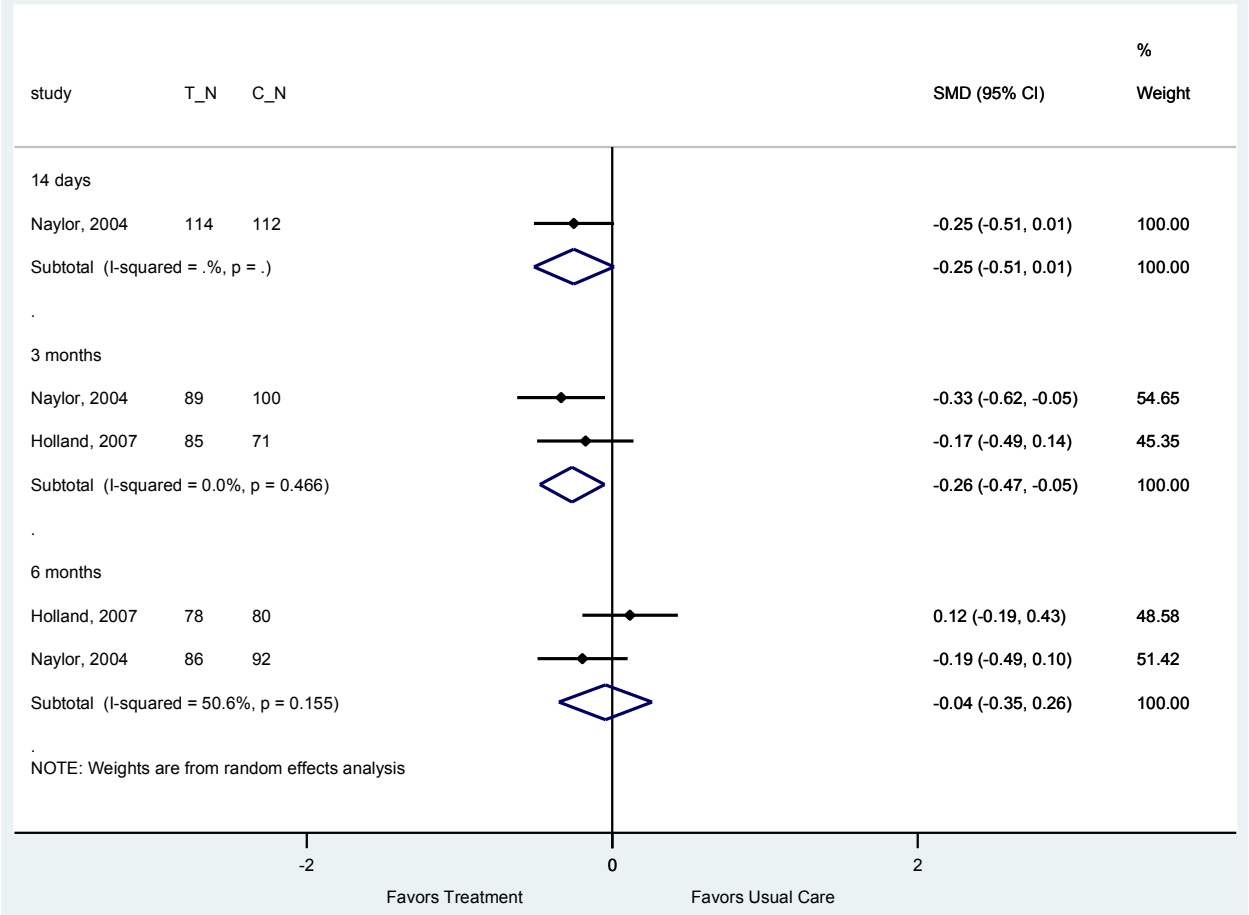


Figure E-8. Difference in mean MLWHFQ scores for structured telephone support interventions compared with usual care, by outcome timing

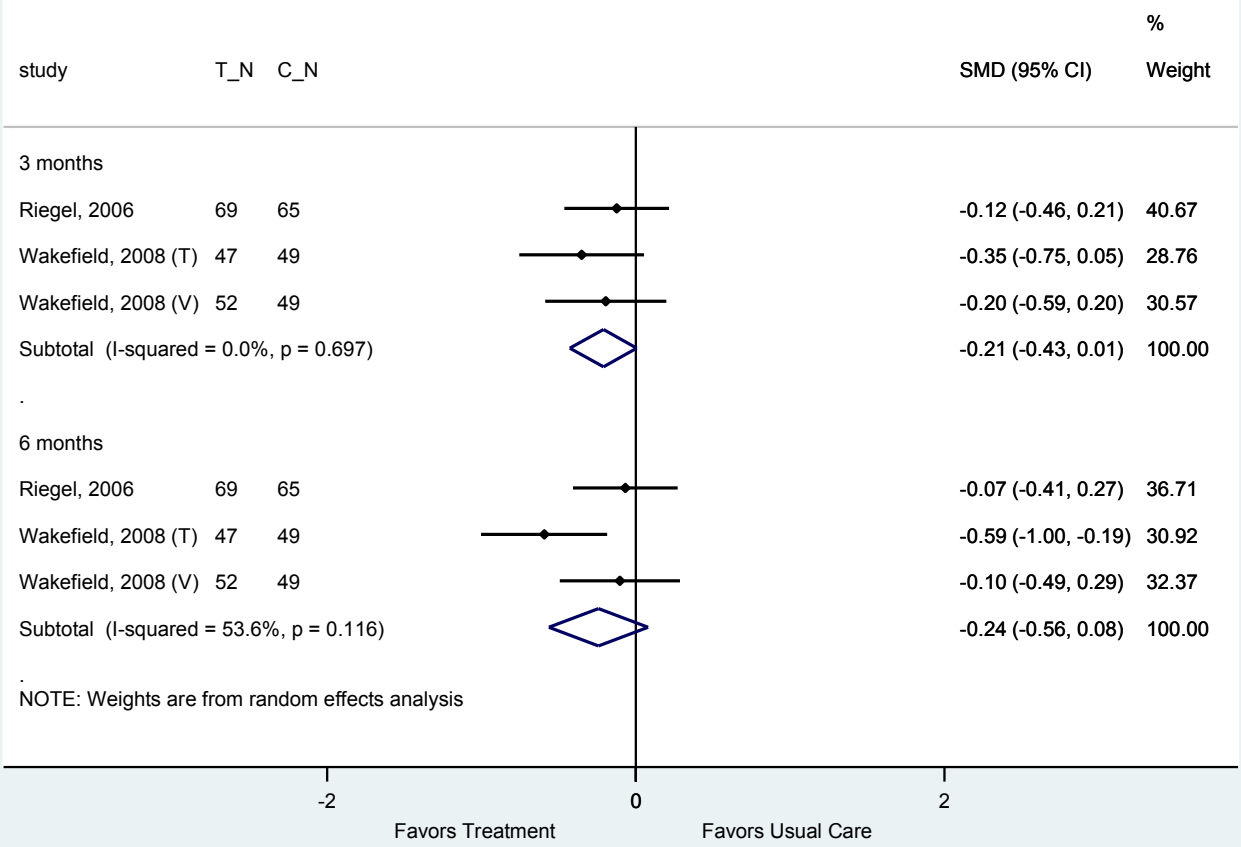


Figure E-9. All-cause readmissions for home-visiting programs compared with usual care, by intensity and outcome timing

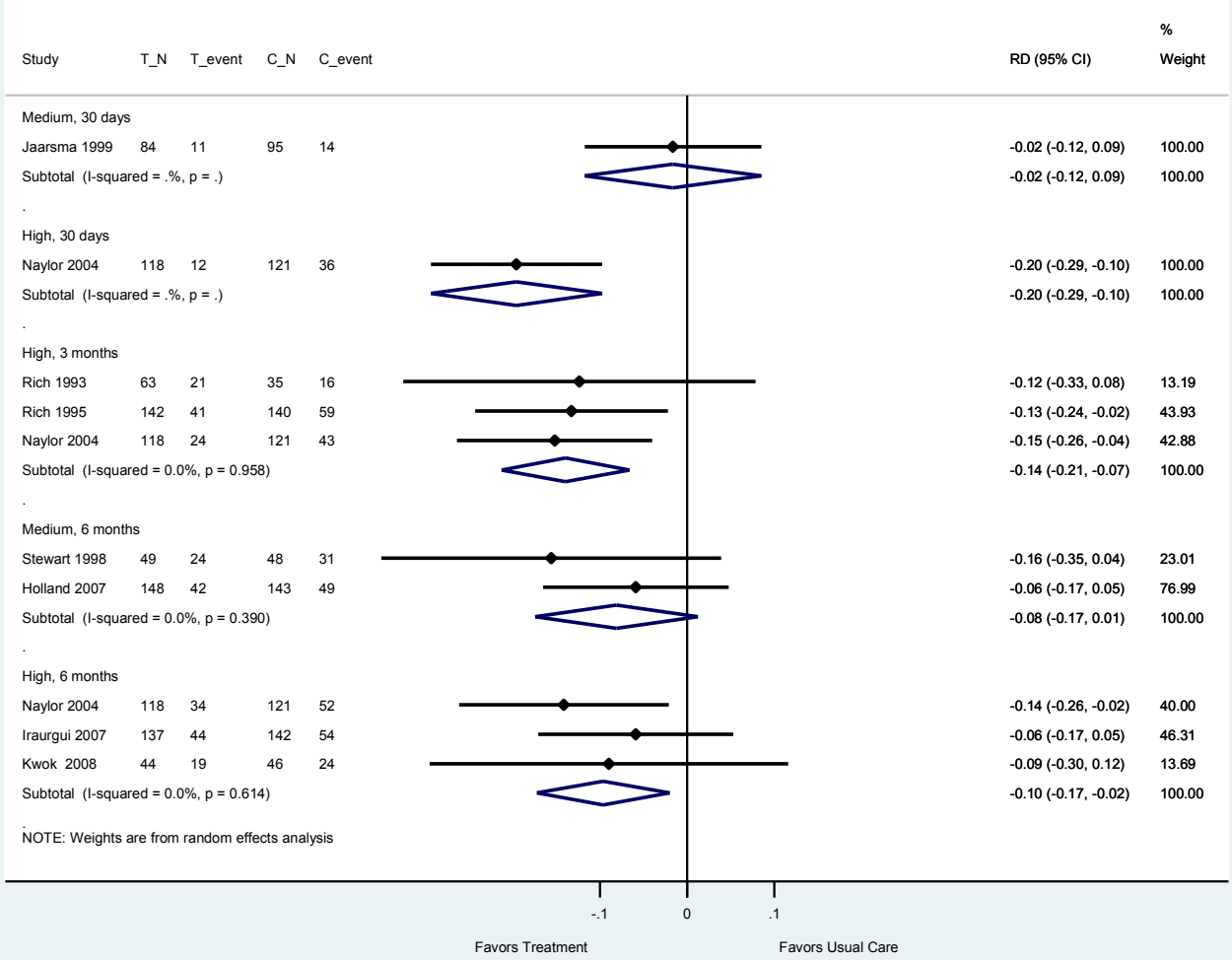


Figure E-10. Mortality for home-visiting programs compared with usual care, by intensity and outcome timing

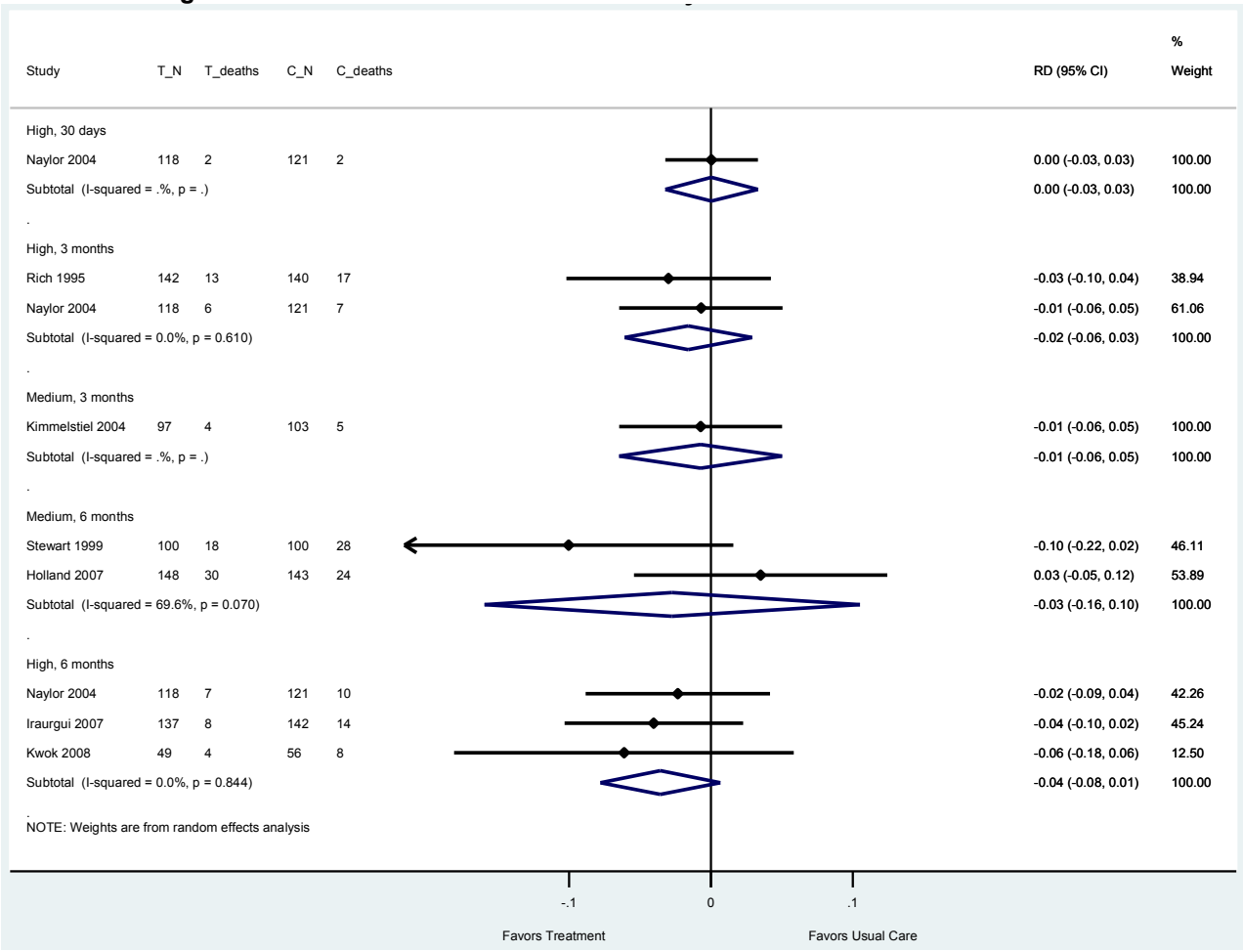


Figure E-11. All-cause readmissions for structured telephone support interventions compared with usual care, by intensity and outcome timing

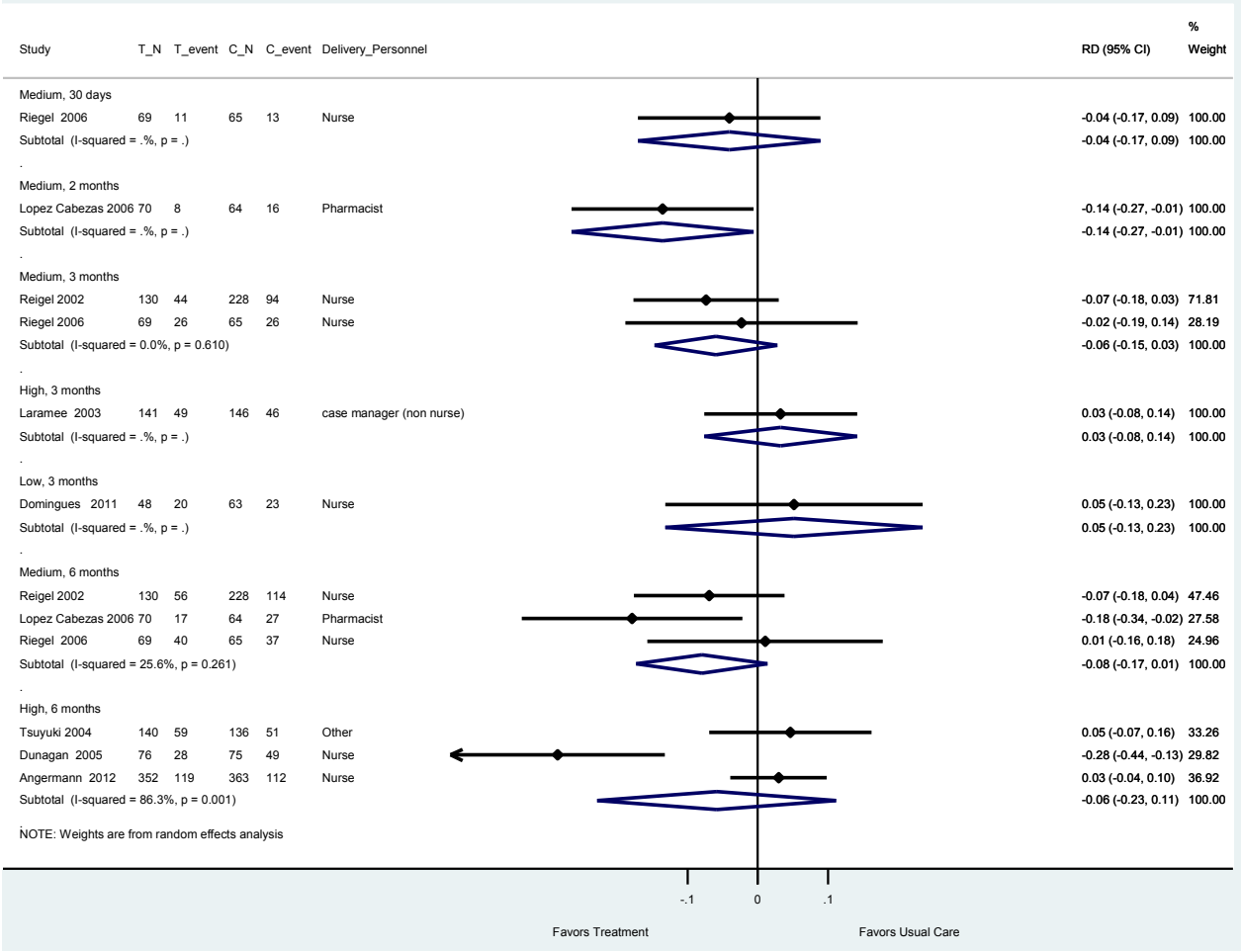


Figure E-12. Mortality for structured telephone support interventions compared with usual care, by intensity and outcome timing

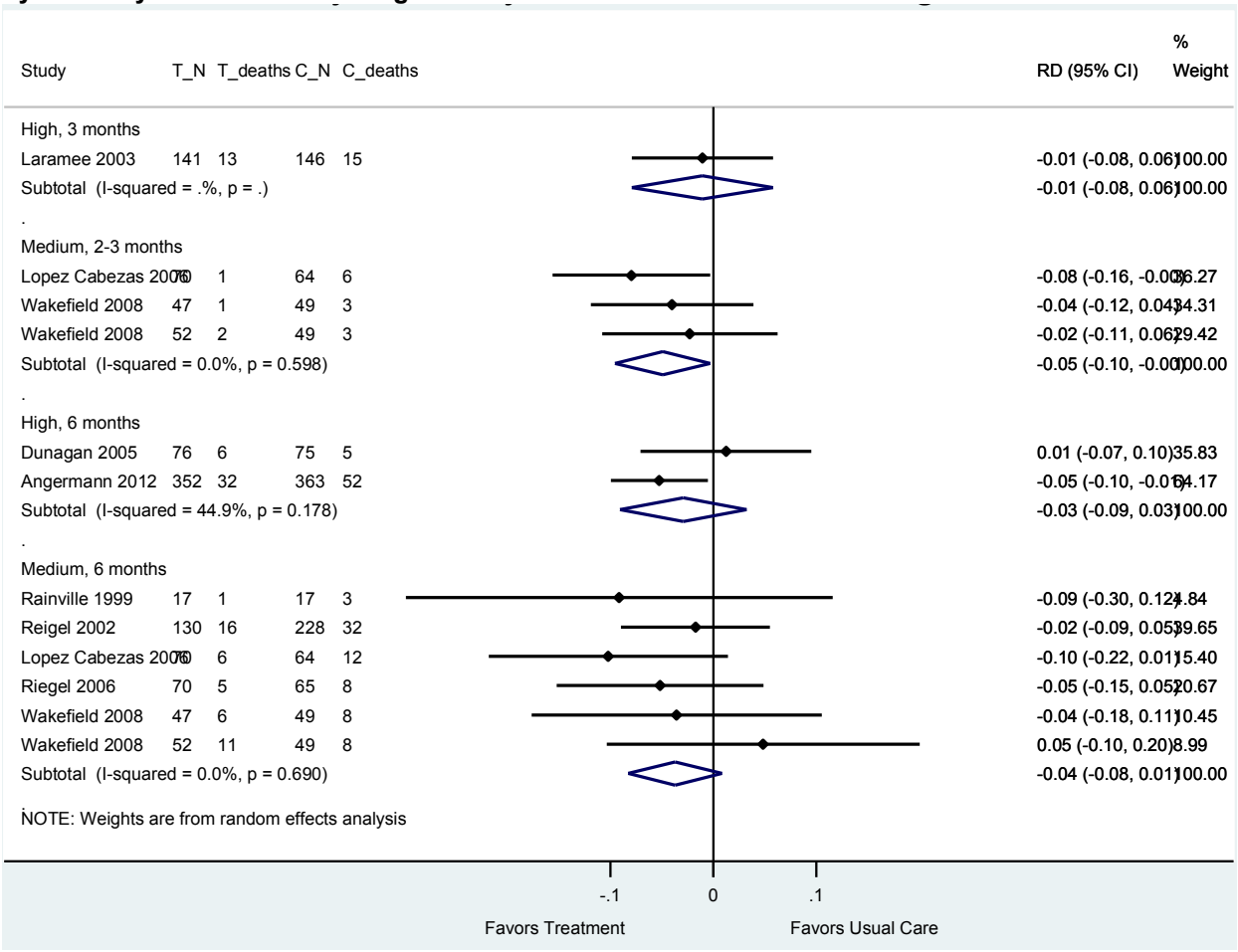


Figure E-13. All-cause readmissions for home-visiting programs compared with usual care, by delivery personnel and outcome timing

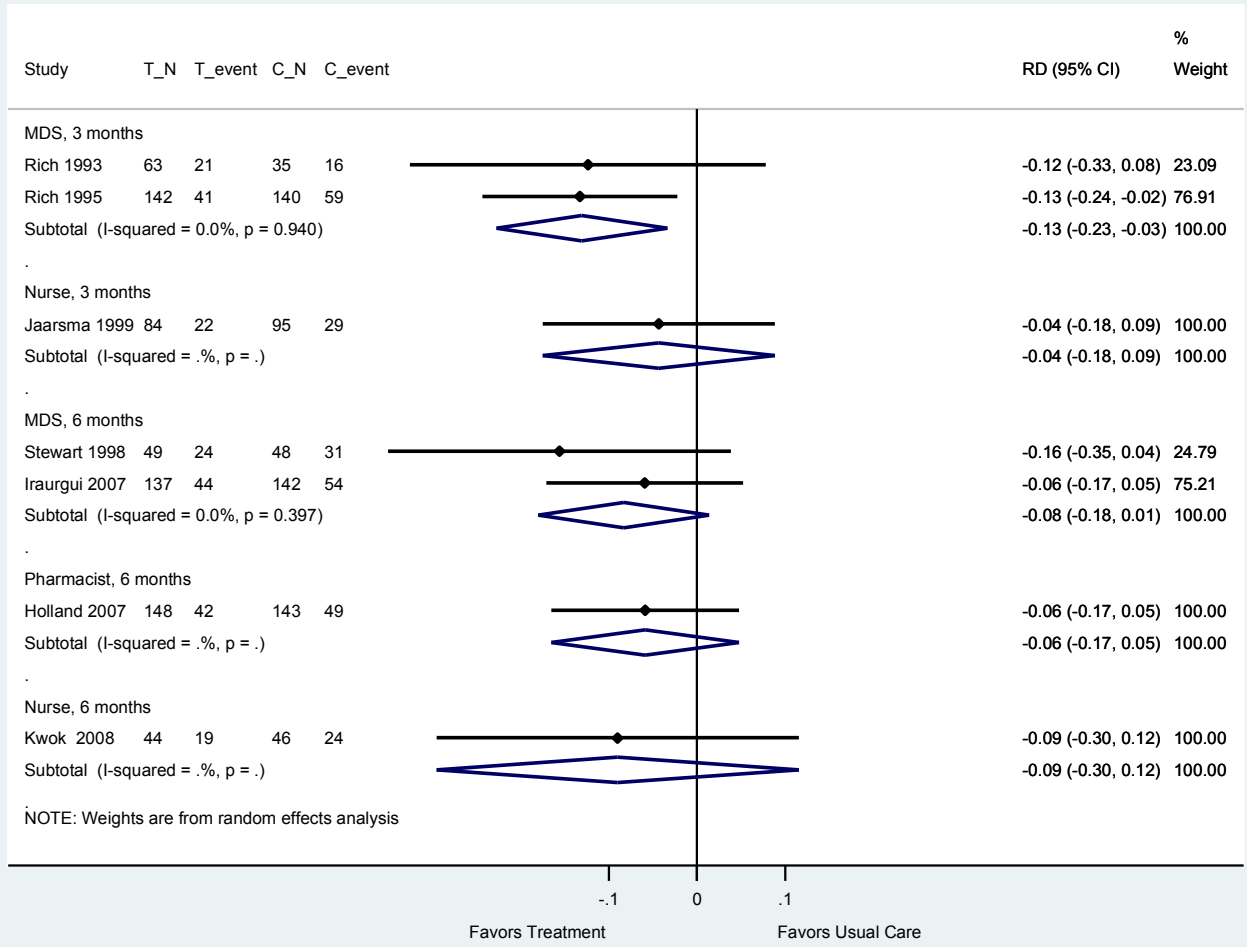


Figure E-14. Mortality for home-visiting programs compared with usual care, by delivery personnel and outcome timing

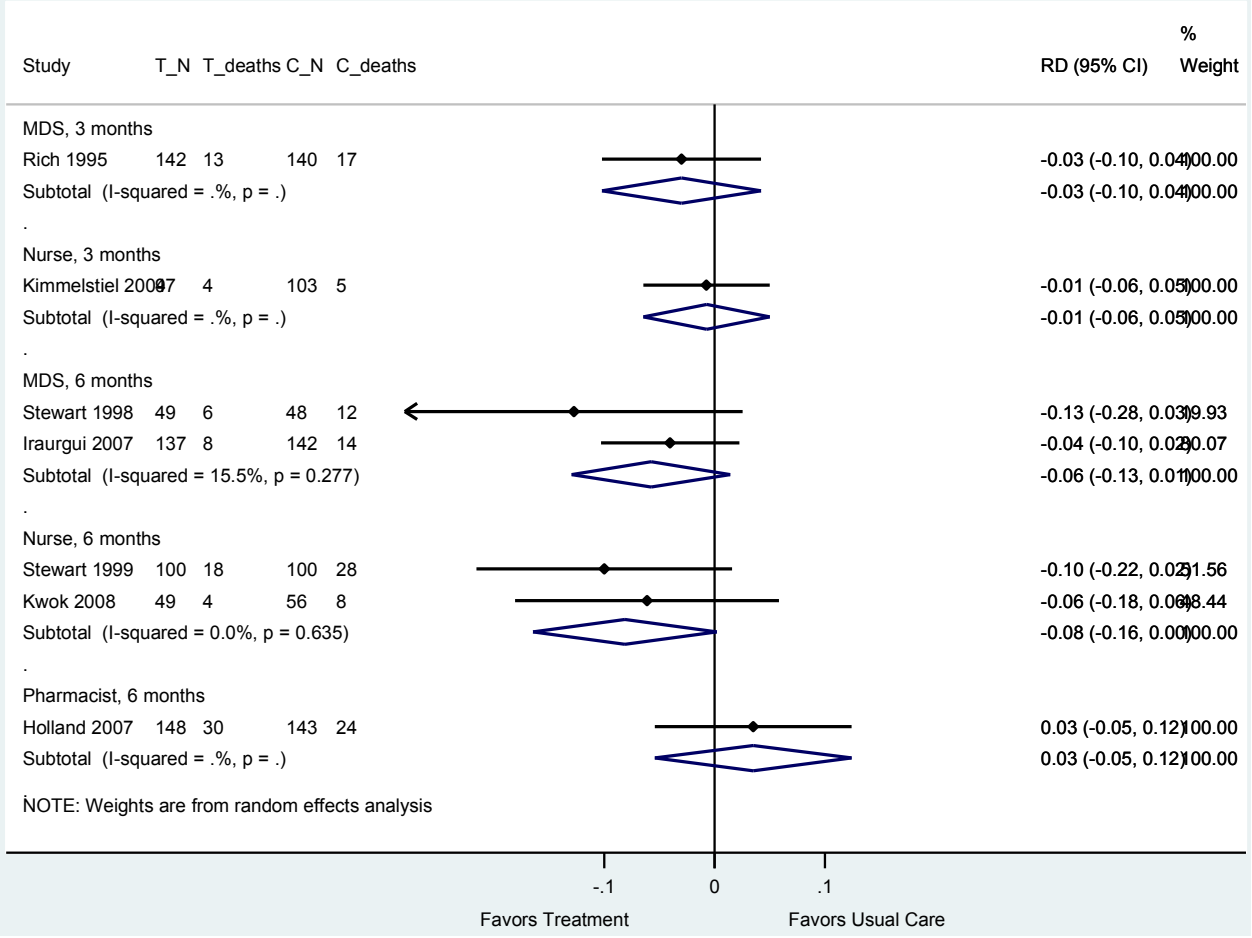


Figure E-15. All-cause readmission for structured telephone support interventions compared with usual care, by delivery personnel and outcome timing

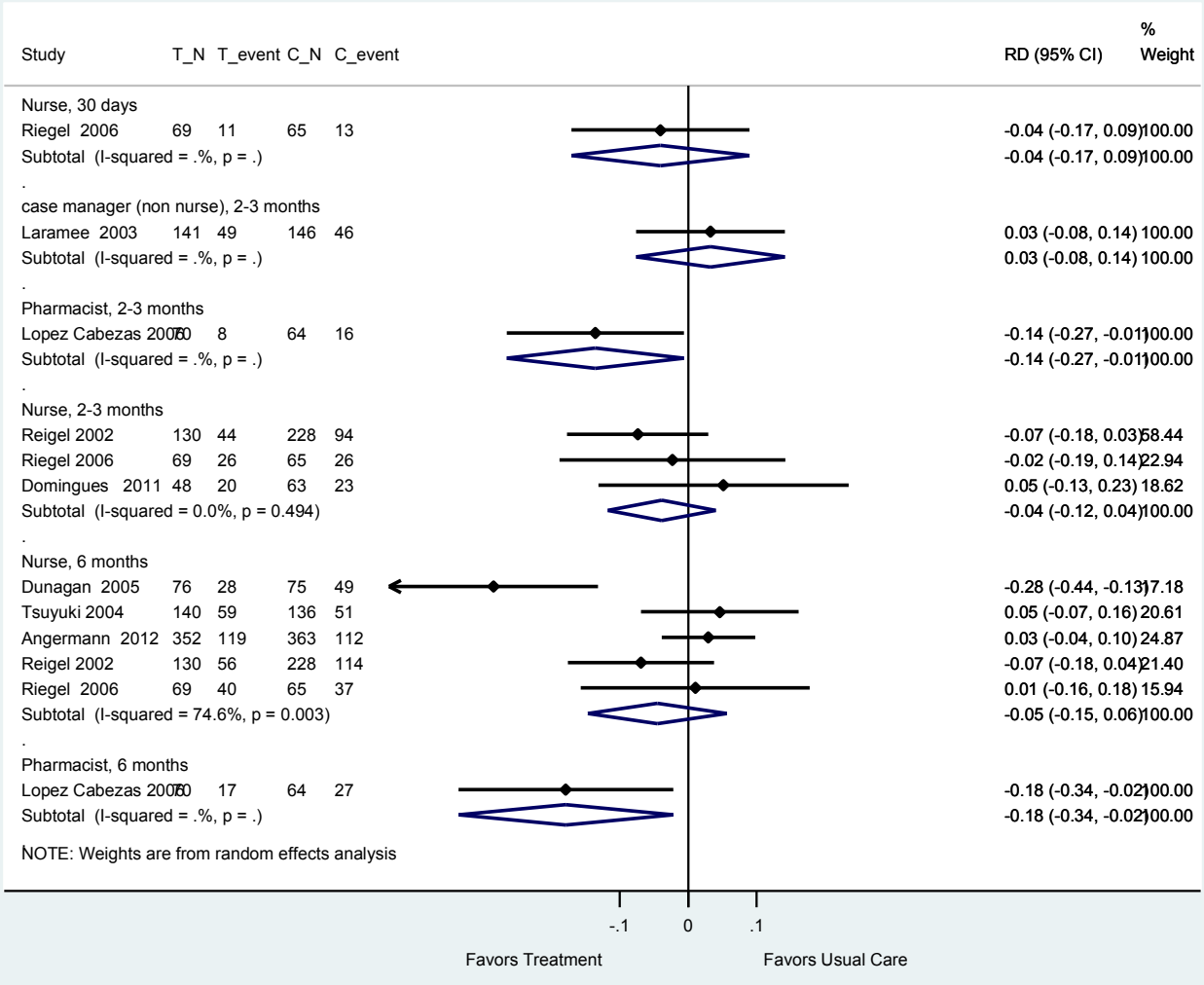


Figure E-16. Mortality for structured telephone support interventions compared with usual care, by delivery personnel and outcome timing

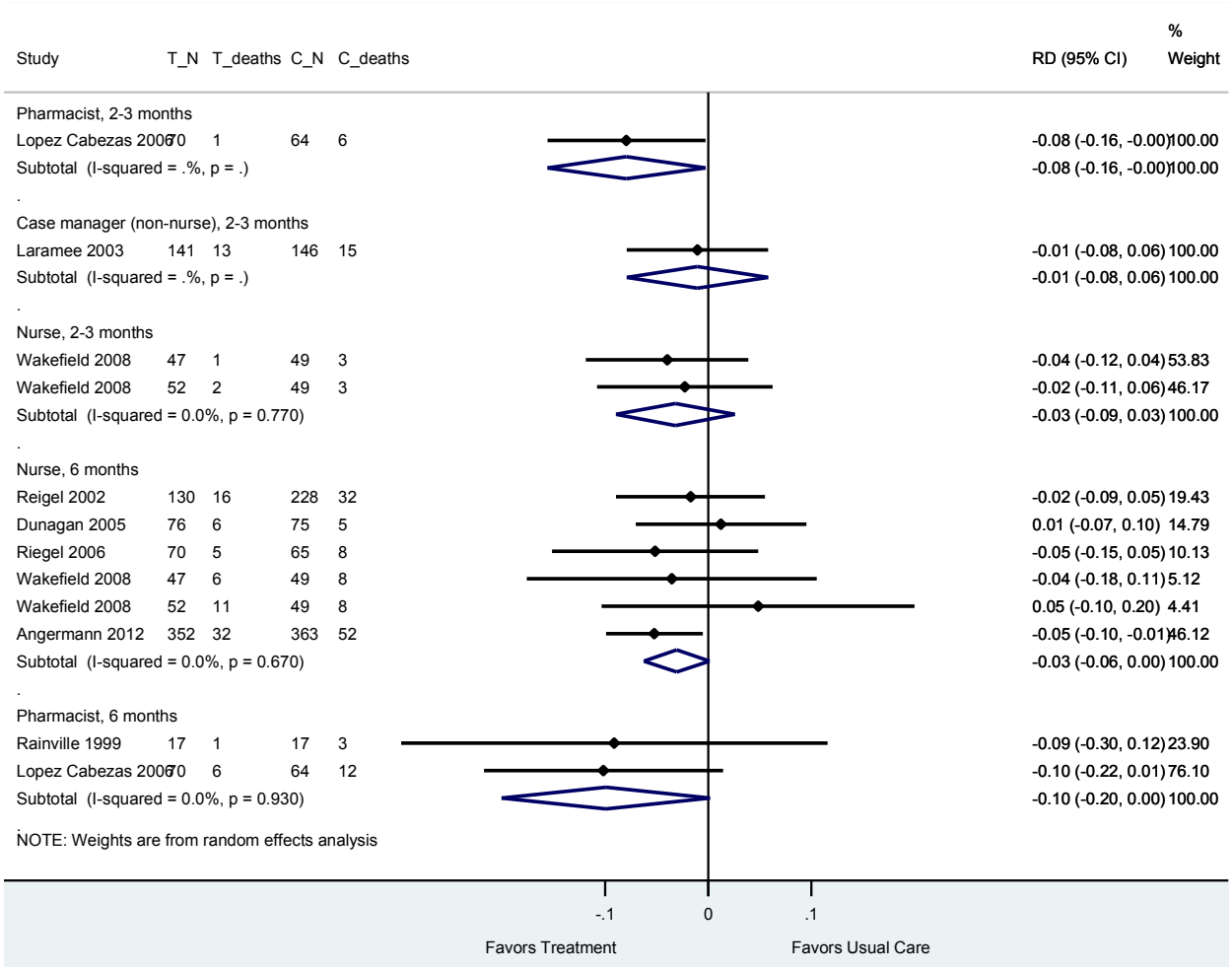


Figure E-17. All-cause readmission for structured telephone support interventions compared with usual care, by method of communication and outcome timing

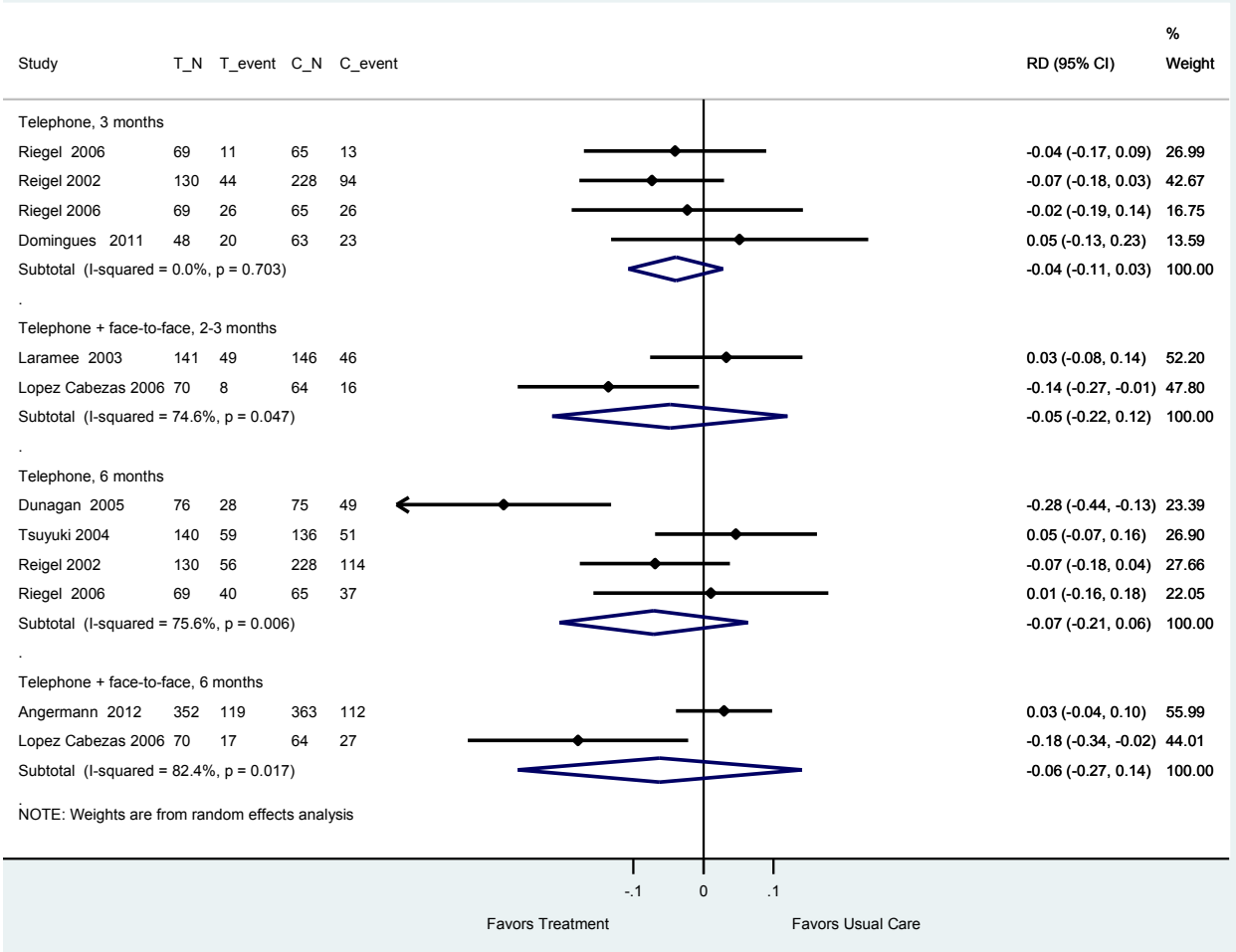
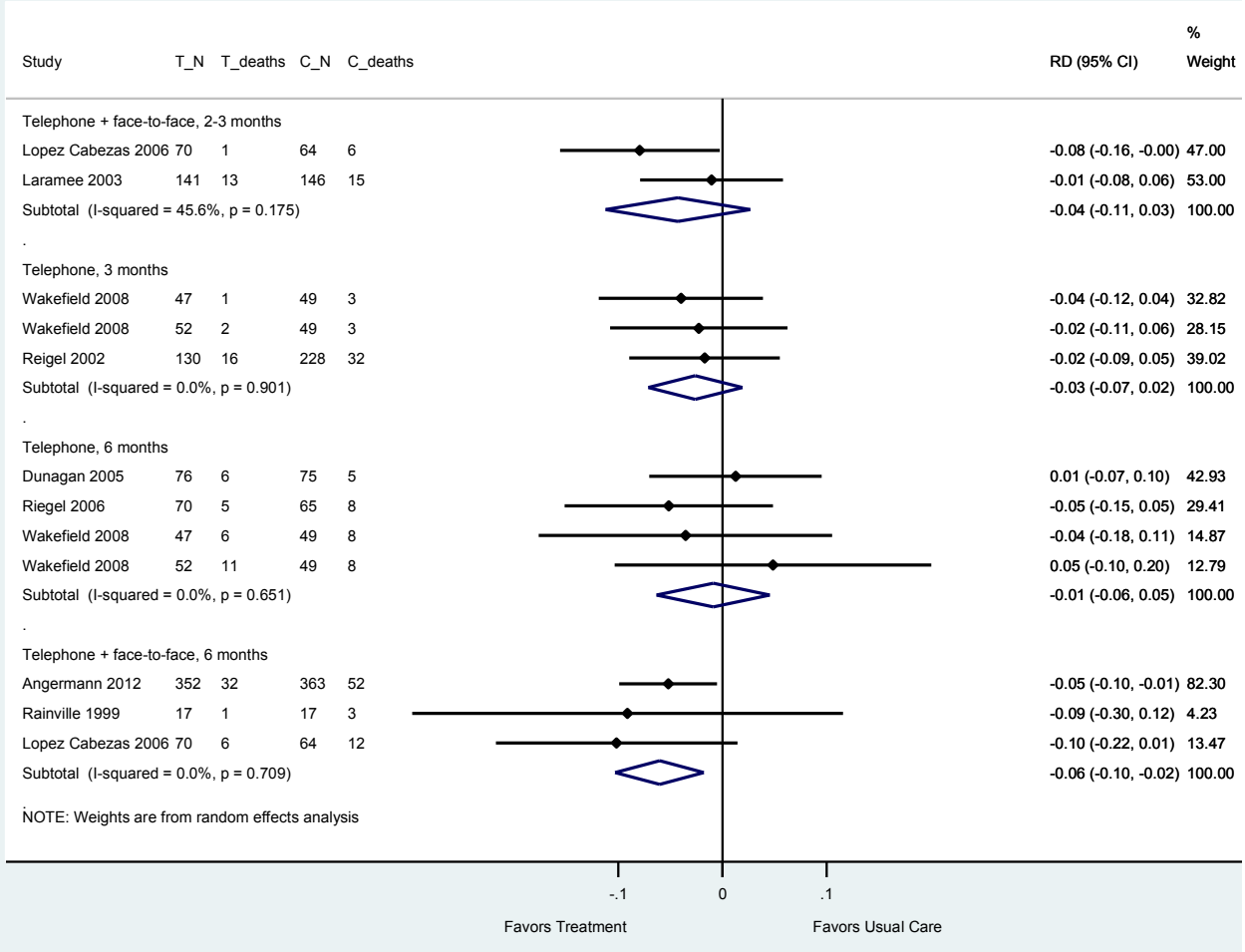


Figure E-18. Mortality for structured telephone support interventions, by method of communication and outcome timing



Appendix F. Sensitivity Analyses

Figure F-1. All-cause readmission for transitional care interventions compared with usual care, by intervention category and outcome timing: Sensitvity analysis including studies rated as having high or unclear ROB

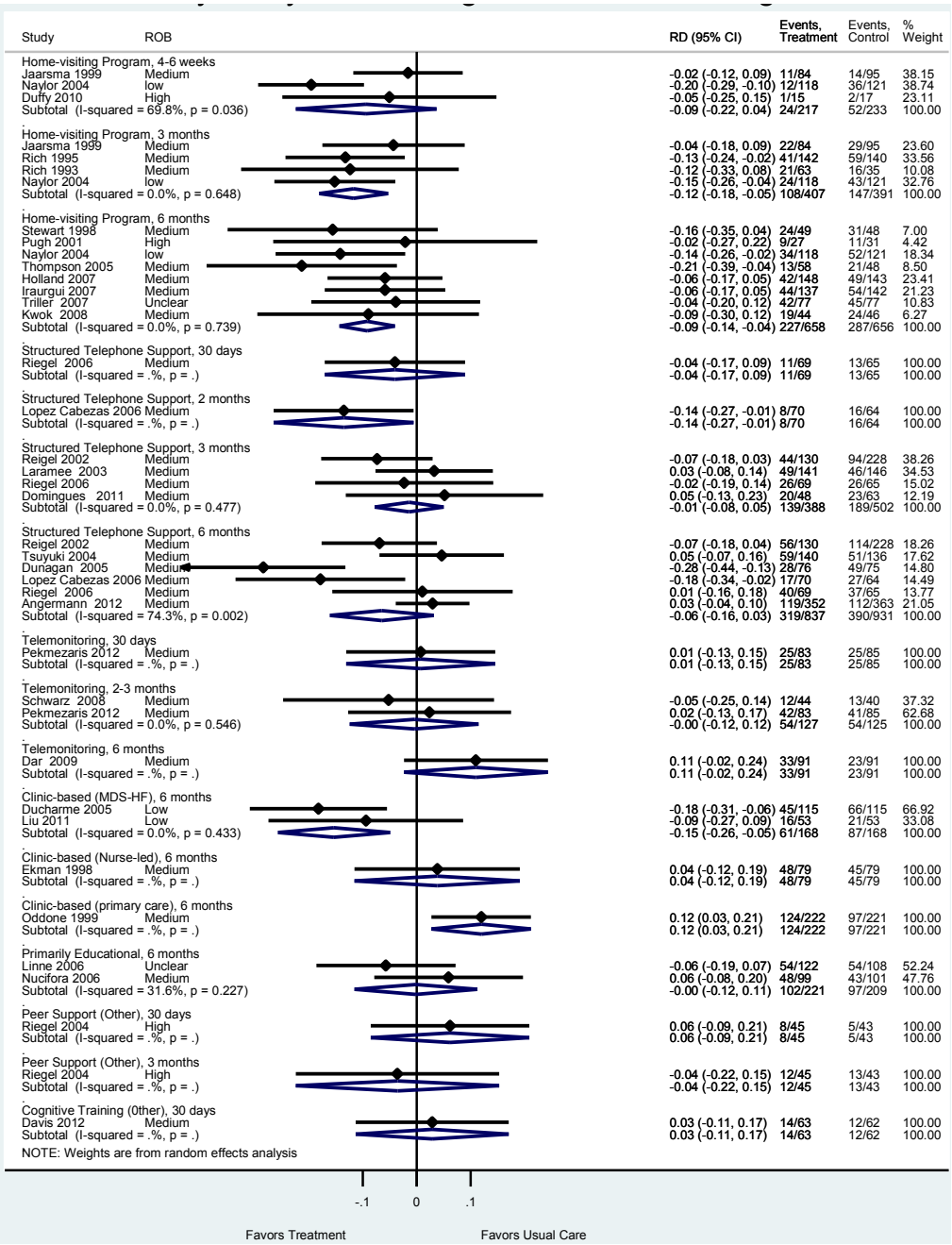


Figure F-2. HF readmissions for transitional care interventions compared with usual care, by intervention category and outcome timing: Sensitvity analysis including studies rated as having high or unclear ROB

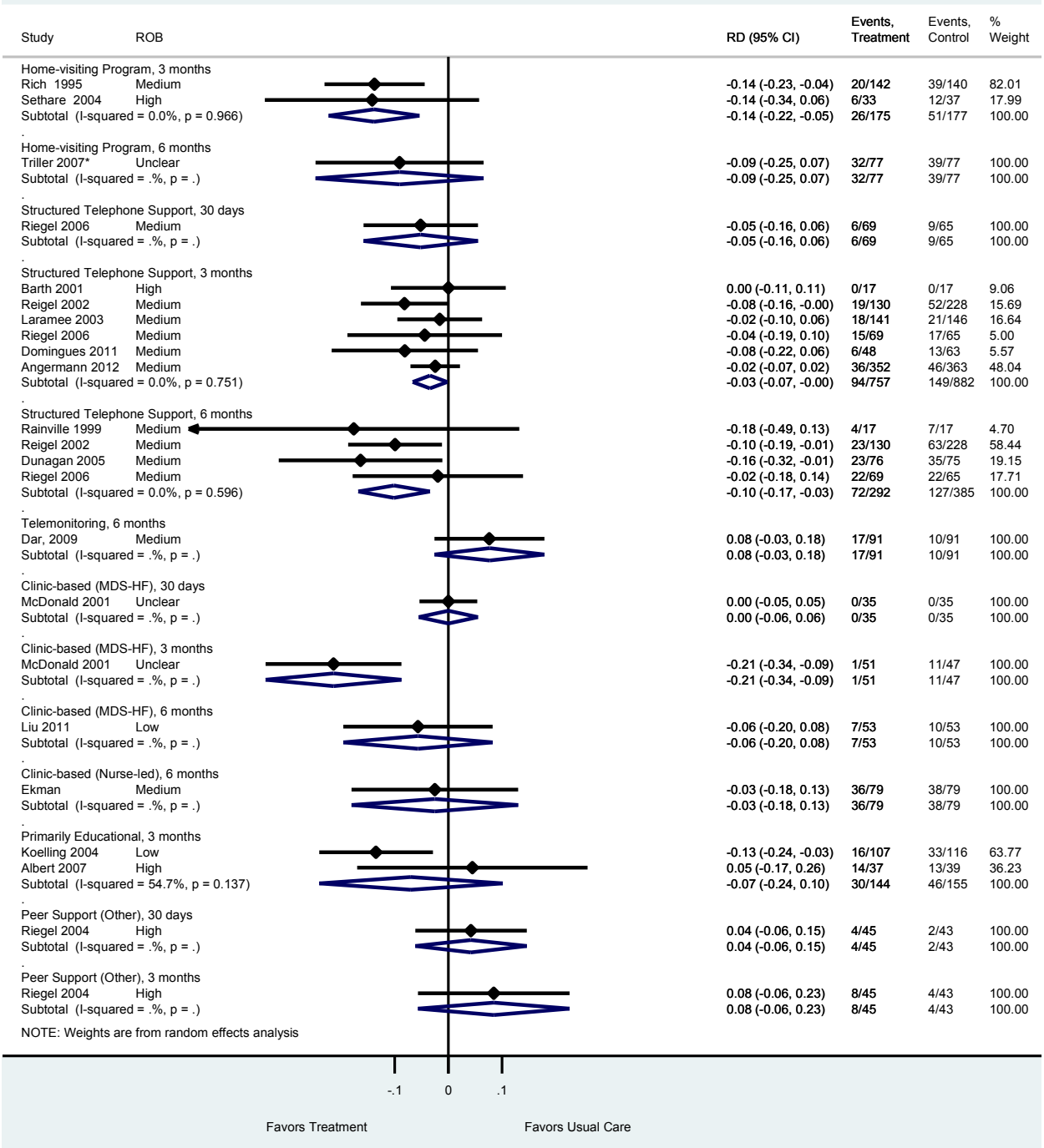


Figure F-3. Combined all-cause readmission or death for transitional care interventions compared with usual care, by intervention category and outcome timing: Sensitvity analysis including studies rated as having high or unclear ROB

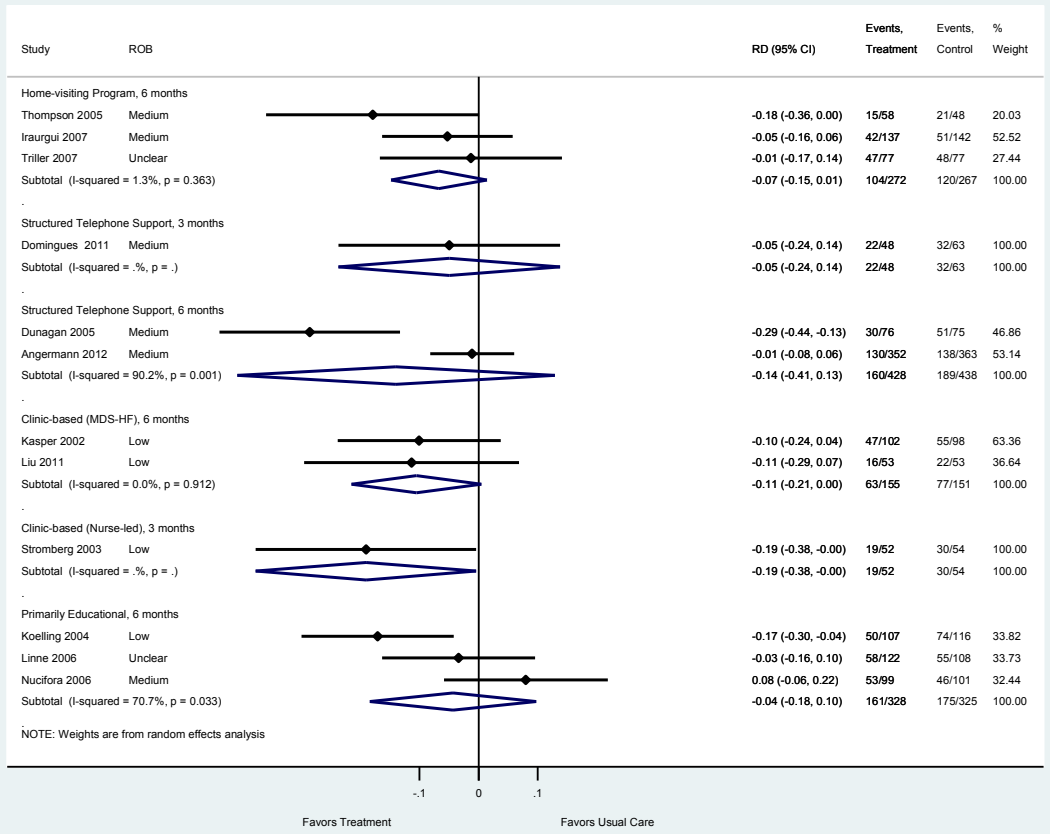
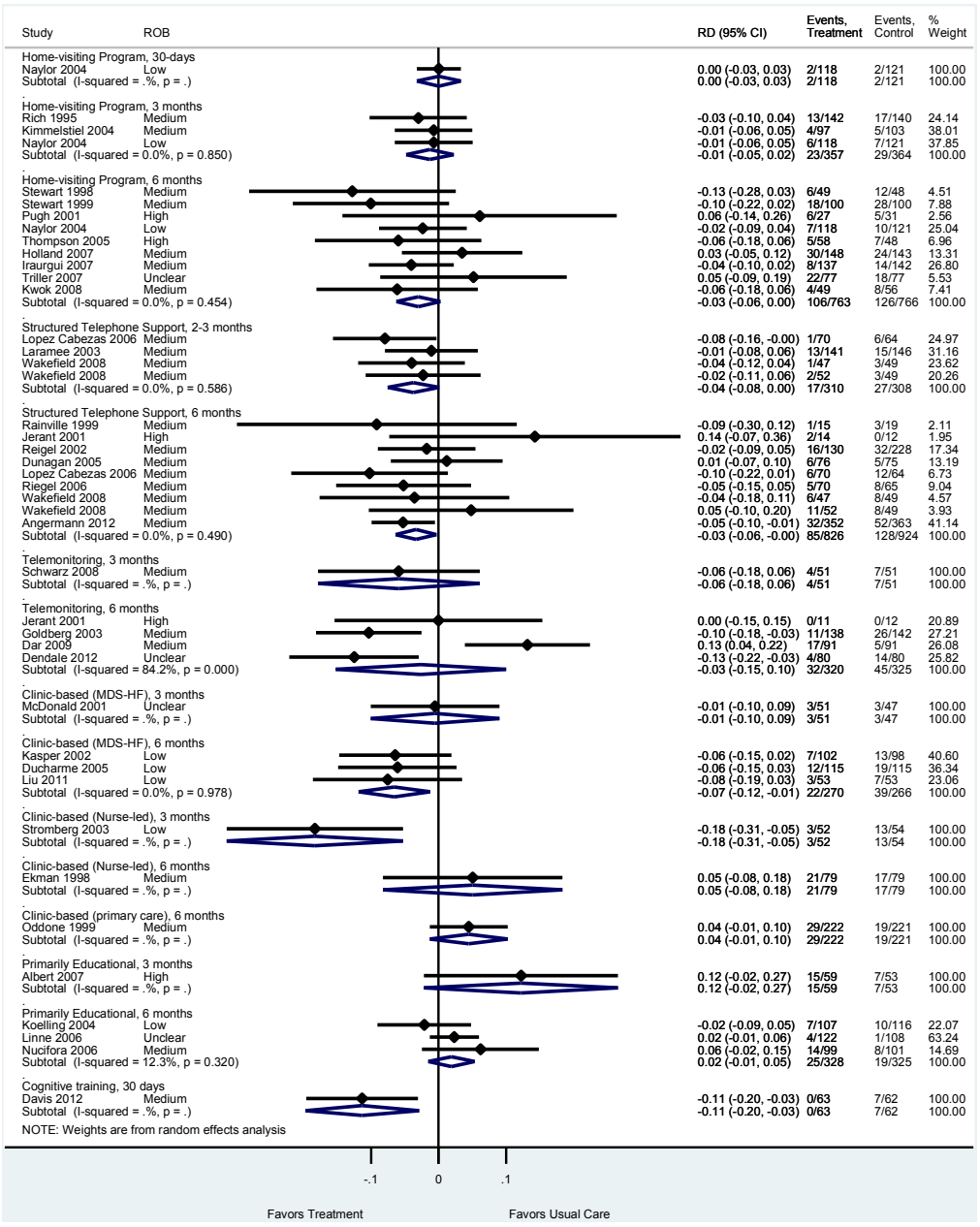


Figure F-4. Mortality for transitional care interventions compared with usual care, by intervention category and outcome timing: Sensitvity analysis including studies rated as having high or unclear ROB



Appendix G. Strength of Evidence Tables

Table G1. All-cause readmission (number of people readmitted): Strength of evidence

Intervention Category; Time-point	Number of Studies; Subjects	Study Limitations	Consistency	Directness	Precision	Findings and Direction[a] [Magnitude] of Effect RD (95% CI)	Strength of Evidence
Home-visiting; 30 days	2; 418	Low	Consistent[b]	Direct	Imprecise	High intensity (1 trial):-0.20 (-0.29 to -0.10) Lower intensity (1 trial): -0.02 (-0.12 to 0.09)	ILow[b]
Home-visiting; 3 months	4; 798	Low	Consistent	Direct	Imprecise	-0.12 (-0.18 to -0.05)	Moderate
Home-visiting; 6 months	6; 1102	Low	Consistent	Direct	Imprecise	-0.10 (-0.16 to -0.05)[b]	Moderate
Structured telephone support; 30 days	1; 134	Low	Unknown	Direct	Imprecise	-0.04 (-0.17 to 0.09)	Insufficient
Structured telephone support; 2-3 months	5; 1024	Low	Consistent	Direct	Imprecise	-0.04 (-0.10 to 0.03)	Moderate
Structured telephone support; 6 months	6; 1768	Low	Inconsistent	Direct	Imprecise	-0.06 (-0.16 to 0.03)	Low
Tele-monitoring; 30 days	1; 168	Low	Unknown	Direct	Imprecise	0.01 (-0.13 to 0.15)	Insufficient
Tele-monitoring; 2-3 months	2; 252	Low	Consistent	Direct	Imprecise	-0.00 (-0.12 to 0.12)	Moderate
Tele-monitoring; 6 months	1; 182	Low	Consistent[c]	Direct	Imprecise	0.11 (-0.02 to 0.24)	Moderate[c]
Clinic-based (nurse-led); 6 months	1; 106	Low	Unknown	Direct	Imprecise	-0.17 (-0.36 to 0.01)	Insufficient
Clinic-based (MDS-HF); 6 months	2; 336	Low	Consistent	Direct	Imprecise	-0.15 (-0.26 to -0.05)	Moderate

Table G1. All-cause readmission (number of people readmitted): Strength of evidence (continued)

Intervention Category; Time-point	Number of Studies; Subjects	Study Limitations	Consistency	Directness	Precision	Findings and Direction[a] [Magnitude] of Effect RD (95% CI)	Strength of Evidence
Clinic-based (Primary Care); 6 months	1; 443	Low	Unknown	Direct	Imprecise	0.12 (0.03 to 0.21)	Insufficient
Primarily Educational; 6 months	1; 200	Low	Unknown	Direct	Imprecise	0.06 (-0.08 to 0.20)	Insufficient
Cognitive Training; 30 days	1; 125	Low	Unknown	Direct	Imprecise	0.03 (-0.11 to 0.17)	Insufficient

[a] Negative values favor the intervention group.

[b]For home-visiting programs, reduction in 30-day all-cause readmission differed by intervention intensity. The one trial assessing a higher intensity intervention showed efficacy[51] while the one trial assessing a lower intensity intervention did not show efficacy.[43] In grading the SOE, we considered results of similar interventions at other time-points. The low SOE refers to the overall assessment that higher intensity home-visiting programs reduce all-cause readmission while lower intensity interventions do not.

[c] Two additional trials reported on the total number of readmissions per group (rather than people readmitted): In one trial (N=200), patients receiving home visits had fewer unplanned readmissions (68) than those receiving usual care (118) (p = 0.031).[46] In another trial (N=200), all-cause readmission did not differ between patients receiving home visits and those receiving usual care (measured as mean readmissions per patient-year alive: RR, 0.89; p=0.61).[49]

[d] Four telemonitoring studies reported the total number of readmissions per group (rather than the number of people readmitted); all-cause readmission did not differ between patients receiving telemonitoring and those receiving usual care at 30 days,[67] 3 months,[77] or 6 months.[67,73,75]

Abbreviations: CI = confidence interval; MDS-HF = multidisciplinary heart failure; N = trial sample size; RCT = randomized controlled trial; RD = risk difference; RR = risk ratio

Table G2. HF-specific readmission (number of people readmitted): Strength of evidence

Intervention Category; Time-point	Number of Studies; Subjects	Study Limitations	Consistency	Directness	Precision	Findings and Direction[a] [Magnitude] of Effect RD (95% CI)	Strength of Evidence
Home-visiting; 3 months	1; 282	Low	Consistent[b]	Direct	Imprecise	-0.14 (-0.23 to -0.04)	Moderate[b]
Structured telephone support; 30 days	1; 134	Low	Unknown	Direct	Imprecise	-0.05 (-0.16 to 0.06)	Insufficient
Structured telephone support; 3 months	5; 1605	Low	Consistent	Direct	Imprecise	-0.04 (-0.07 to -0.00)	Moderate
Structured telephone support; 6 months	4; 677	Low	Consistent	Direct	Imprecise	-0.10 (-0.17 to -0.03)	Moderate
Tele-monitoring; 6 months	1; 182	Low	Consistent[c]	Direct	Imprecise	0.08 (-0.03 to 0.18)	Moderate[c]
Clinic-based (Nurse-led) 6 months	1; 158	Low	Unknown	Direct	Imprecise	-0.03 (-0.18 to 0.13)	Insufficient
Clinic-based (MDS-HF) 6 months	1; 106	Low	Unknown	Direct	Imprecise	-0.06 (-0.20 to 0.08)	Insufficient
Primarily Educational 3 months	1; 223	Low	Unknown	Direct	Imprecise	-0.13 (-0.24 to -0.03)	Insufficient

[a] Negative values favor the intervention group.

[b] Although one trial reported total number of people readmitted per group, we considered the findings consistent due to the fact that one other trial reported on the number of readmissions per group and found a similar effect: patients receiving home visits had fewer total HF readmissions than did patients receiving usual care (measured as readmissions per patient year alive, RR, 0.54; $p<0.001$; N=200).[49]

c Although one trial reported total number of people readmitted per group, we considered the findings consistent due to the fact that two other trial reported on the number of readmissions per group neither study found a difference between the intervention and control group two groups.[73,75]

Abbreviations: CI = confidence interval; HF = heart failure; MDS-HF = multidisciplinary heart failure; N = trial sample size; RD = risk difference; RR = risk ratio.

Table G3. Combined all-cause readmission or death: Strength of evidence

Intervention Category; Time-point	Number of Studies; Subjects	Study Limitations	Consistency	Directness	Precision	Findings and Direction [Magnitude] of Effect[a]	Strength of Evidence
Home-visiting; 30 days	1; 239	Low	Unknown	Direct	Imprecise	HR (SE): 0.869 (0.033) vs. 0.737 (0.041)	Low[b]
Home-visiting; 3 months	1; 239	Low	Unknown	Direct	Imprecise	HR (SE): 0.071 (0.045) vs. 0.558 (0.047)	Low[b]
Home-visiting; 6 months	4; 824	Low	Consistent	Direct	Imprecise	3 trials (N=585): RD (95% CI): -0.10 (-0.18 to -0.02) 1 trial (N=239): HR (SE): 0.600 (0.047) vs. 0.444 (0.047)	Moderate
Structured telephone support; 3 months	1; 111	Low	Unknown	Direct	Imprecise	RD (95% CI): -0.05 (-0.24 to 0.14)	Insufficient
Structured telephone support; 6 months	2; 866	Low	Inconsistent	Direct	Imprecise	RD (95% CI): -0.14 (-0.41 to 0.13)	Low
Clinic-based (Nurse-led); 3 months	1; 106	Low	Unknown	Direct	Imprecise	RD (95% CI): -0.19 (-0.38 to -0.00)	Insufficient
Clinic-based (MDS-HF); 6 months	2; 306	Low	Consistent	Direct	Imprecise	RD (95% CI): -0.11 (-0.21 to 0.00)	Moderate
Primarily Educational; 6 months	2; 423	Low	Inconsistent	Direct	Imprecise	RD (95% CI): -0.05 (-0.29 to 0.20)	Low

[a] For RDs, negative values favor the intervention group.

[b] Although evidence was limited to 1 trial, consistency for the 30-day outcome was unknown, and evidence was imprecise, we upgraded the SOE because this intervention category has demonstrated efficacy for this outcome at different time points—thus, increasing our confidence in the results of this single trial.

Abbreviations: CI = confidence interval; HR = hazard ratio; MDS-HF = multidisciplinary heart failure; N = trial sample size; RD = risk difference; SE = standard error; SOE = strength of evidence.

Table G4. Emergency room or acute care visits

Intervention Category; Time-point	Number of Studies; Subjects	Study Limitations	Consistency	Directness	Precision	Findings and Direction [Magnitude] of Effect[a]	Strength of Evidence
Home-visiting; 30 days	1; 179	Medium	Unknown	Direct	Imprecise	% of subjects with ER visits, (intervention vs. control): 5% vs. 4%, p-value NR	Insufficient
Home-visiting; 3 months	1; 179	Medium	Unknown	Direct	Imprecise	% of subjects with ER visits (intervention vs. control): 17% vs. 22%, p-value NR	Insufficient
Home-visiting; 6 months	1; 97	Medium	Unknown	Direct	Imprecise	Total ER visits per group (intervention vs. control): 48 vs. 87 visits, p=0.05	Insufficient
Structured telephone support; 3 months	1; 111	Medium	Unknown	Direct	Imprecise	Total ER visits per group: RR (95% CI): 0.66 (0.21 to 2.05)	Insufficient
Structured telephone support; 6 months	2; 634	Medium	Consistent	Direct	Imprecise	% of patients with at least one ER visit (intervention vs. control): 22.1 vs. 27.9, p=0.266 Mean ER visits per person (intervention vs. control): 0.14 vs. 0.11, p=0.58	Low
Telemonitoring 3 months	1; 102	Medium	Unknown	Direct	Imprecise	Average ER visits per patient (intervention vs. control): 0.34 vs. 0.38, p=0.73	Insufficient
Telemonitoring 6 months	1; 182	Medium	Unknown	Direct	Imprecise	Total ER visits per group (intervention vs. control): 20 vs. 32, p-value NR	Insufficient
Clinic-based (MDS-HF); 6 months	1; 230	Medium	Unknown	Direct	Imprecise	Number of patients per group with ER visits: HR (95% CI): 0.97 (0.70 to 1.36)	Insufficient
Primarily Educational; 3 months	1; 76	Medium	Unknown	Direct	Imprecise	% of patients per group seen in ER (intervention vs. control): 38 vs. 33, p=0.68	Insufficient

[a] For RRs and HRs, values less than 1.0 favor the intervention group.

Abbreviations: CI = confidence interval; ER = emergency room; HR = hazard ratio; MDS-HF = multidisciplinary heart failure; NR = not reported; RD = risk difference; RR = risk ratio.

Table G5. Hospital Days (of subsequent readmissions)

Intervention Category; Time-point	Number of Studies; Subjects	Study Limitations	Consistency	Directness	Precision	Findings and Direction [Magnitude] of Effect[a]	Strength of Evidence
Home-visiting; 30 days	1; 179	Medium	Unknown	Direct	Imprecise	Mean number of readmission days per person readmitted (SD) (intervention vs. control): 2.2 (7) vs. 2.3 (7)	Insufficient
Home-visiting; 3 months	4; 765	Medium	Consistent	Direct	Imprecise	Difference in total hospital days per group: WMD (95% CI): -1.17 (-2.44 to 0.09)	Low
Home-visiting; 6 months	3; 403	Medium	Consistent	Direct	Imprecise	Total hospital days (intervention vs. control, p=value): 261 vs. 452, p=0.05 875 vs. 1476, p=0.04 108 vs. 459, p≤0.01	Low
Structured telephone support; 30 days	1; 134	Medium	Unknown	Direct	Imprecise	WMD (95% CI): -0.95 (-2.43 to 0.53)	Insufficient
Structured telephone support; 2-3 months	4; 882	Medium	Consistent	Direct	Imprecise	WMD (95% CI): -1.43 (-2.35 to -0.51)	Low
Structured telephone support; 6 months	4; 812	Medium	Consistent	Direct	Imprecise	WMD (95% CI): -2.42 (-4.44 to -0.39)	Low
Telemonitoring 30 days	1; 168	Medium	Unknown	Direct	Imprecise	Mean length of hospital stay per patient readmitted (SD) (intervention vs. control): 1.9 (4.4) vs. 1.8 (12.2)	Insufficient
Telemonitoring 3 months	1; 168	Medium	Unknown	Direct	Imprecise	Mean length of hospital stay per patient readmitted (SD) (intervention vs. control): 4.9 (8.2) vs. 4.8 (10.2)	Insufficient

Table G5. Hospital Days (of subsequent readmissions) (continued)

Intervention Category; Time-point	Number of Studies; Subjects	Study Limitations	Consistency	Directness	Precision	Findings and Direction [Magnitude] of Effect[a]	Strength of Evidence
Telemonitoring 6 months	1; 182	Medium	Unknown	Direct	Imprecise	Median duration of readmission hospital stay (intervention vs. control): 17 vs. 13 days, p= 0.99	Insufficient
Clinic-based (Nurse-led); 3 months	1; 106	Medium	Inconsistent	Direct	Imprecise	Total hospital days per group (intervention vs. control): 350 vs. 592, p=0.045	Insufficient
Clinic-based (Nurse-led); 6 months	1; 154	Medium	Unknown	Direct	Imprecise	Mean hospital days per patient readmitted (SD) (intervention vs. control): 26 (19) vs. 18 (19); p-value NS per investigators	Insufficient
Clinic-based (MDS-HF); 6 months	1; 230	Medium	Unknown	Direct	Imprecise	Total hospital days per patient (intervention vs. control): Hazard ratio (95% CI): 0.61 (0.39 to 0.95)	Insufficient
Clinic-based (primary-care); 6 months	1; 443	Medium	Unknown	Direct	Imprecise	Mean hospital days per patient readmitted (intervention vs. control): 9.1 vs. 7.3, p=0.04	Insufficient
Primarily Educational; 3 months	1; 200	Medium	Unknown	Direct	Imprecise	Mean length of hospital stay per person readmitted: 20 vs. 15 days, p-value NS per authors	Insufficient

[a] Negative values favor the intervention group (for WMD).

Abbreviations: CI = confidence interval; HR = hazard ratio; MDS-HF = multidisciplinary heart failure; NS = not significant; SD = standard deviation; WMD = weighted mean difference.

Table G6. Quality of Life (MLWHFQ) by outcome timing – home-visiting programs versus usual care: Strength of evidence

Intervention Category; Time-point	Number of Studies; Subjects Analyzed	Study Limitations	Consistency	Directness	Precision	Findings and Direction [Magnitude] of Effect[a]	Strength of Evidence
Home-visiting; 14 days	1; 226	Medium	Unknown	Direct	Imprecise	No difference in mean MLWHFQ score at 14 days	Insufficient
Home-visiting; 3 months	3; 345	Medium	Consistent	Direct	Imprecise	2 trials: SMD (95% CI): -0.26 (-0.47 to -0.05).[51,55] One trial (N=200): mean MLWHFQ (change from baseline, intervention vs. control): -19 vs. -1, p=0.04.[46]	Low
Home-visiting; 6 months	2; 384	Medium	Inconsistent	Direct	Imprecise	Difference in mean score at 6 months: SMD (95% CI): -0.04 (-0.35 to 0.26)	Low
Structured telephone support; 3 months	3; 331	Medium	Consistent	Direct	Imprecise	Difference in mean scores at 3 months: WMD (95% CI): -3.04 (-6.74 to 0.66)	Low
Structured telephone support; 6 months	3; 331	Medium	Consistent	Direct	Imprecise	Difference in mean scores at 3 months: WMD (95% CI): -5.27 (-13.45 to 2.91)	Low
Telemonitoring 3 months	1; 102	Medium	Unknown	Direct	Imprecise	Difference in mean scores at 3 months: 27.4 vs. 27.3, p=0.99	Insufficient
Clinic-based Interventions 6 months	1; 200	Medium	Unknown	Direct	Imprecise	MLWHFQ change from baseline: -28.3 vs. -15.7, p=0.01	Insufficient
Primarily Educational 6 months	2; 372	Medium	Inconsistent	Direct	Imprecise	One trial (N=223): mean MLWHFQ (SD) (intervention vs. control): 14 (20) vs. 10 (16), p<0.0001]. Another trial (N=149): mean MLWHFQ (SD) (intervention vs. control): 41 (22) vs. 42 (25), p-value NR.	Low

[a] For SMDs and WMDs, negative values favor the intervention group.

Abbreviations: CI = confidence interval; MLWHFQ = Minnesota Living With Heart Failure Questionnaire; N = trial sample size; NR = not reported; SD = standard deviation; SMD = standardized mean difference; WMD = weighted mean difference.

Table G7. Mortality: Strength of evidence

Intervention Category; Time-point	Number of Studies; Subjects	Study Limitations	Consistency	Directness	Precision	Findings and Direction [Magnitude] of Effect RD (95% CI)[a]	Strength of Evidence
Home-visiting; 30 days	1; 239	Low	Unknown	Direct	Imprecise	0.00 (-0.03, 0.03)	Low[a]
Home-visiting; 3 months	3; 721	Low	Consistent	Direct	Imprecise	-0.01 (-0.05 to 0.02)	Moderate
Home-visiting; 6 months	6; 1211	Low	Consistent	Direct	Imprecise	-0.04 (-0.07 to 0.00)	Moderate
Structured telephone support; 2-3 months	3; 618	Low	Consistent	Direct	Imprecise	-0.04 (-0.08 to 0.00)	Moderate
Structured telephone support; 6 months	8; 1724	Low	Consistent	Direct	Imprecise	-0.04 (-0.07 to -0.01)	Moderate
Telemonitoring 3 months	2; 284	Low	Inconsistent	Direct	Imprecise	0.00 (-0.10 to 0.10)	Low
Telemonitoring 6 months	2; 462	Low	Inconsistent	Direct	Imprecise	0.01 (-0.22 to 0.24)	Low
Clinic-based (Nurse-led); 3 months	1; 106	Low	Unknown	Direct	Imprecise	-0.18 (-0.31 to -0.05)	Insufficient

Table G7. Mortality: Strength of evidence (continued)

Intervention Category; Time-point	Number of Studies; Subjects	Study Limitations	Consistency	Directness	Precision	Findings and Direction [Magnitude] of Effect RD (95% CI)[a]	Strength of Evidence
Clinic-based (Nurse-led); 6 months	1; 158	Low	Unknown	Direct	Imprecise	0.05 (-0.08 to 0.18)	Insufficient
Clinic-based (MDS-HF); 6 months	3; 536	Low	Consistent	Direct	Imprecise	-0.07 (-0.12 to -0.01)	Moderate
Clinic-based (primary care); 6 months	1; 443	Low	Unknown	Direct	Imprecise	0.04 (-0.01 to 0.10)	Insufficient
Primarily Educational; 6 months	2; 423	Low	Inconsistent	Direct	Imprecise	0.02 (-0.07 to 0.10)	Low
Cognitive Training 30 days	1; 125	Low	Unknown	Direct	Imprecise	-0.11 (-0.20 to -0.03)	Insufficient

[a] Negative values favor the intervention.

[b] Although evidence was limited to 1 trial, consistency for the 30-day outcome was unknown, and evidence was imprecise, we upgraded the SOE because this intervention category has demonstrated no effect on mortality at 3 or 6 months—thus, increasing our confidence in the results of this single trial.

Abbreviations: CI = confidence interval; MDS-HF = multidisciplinary heart failure; RD = risk difference.